IRRS
Integrated Regulatory
Review System
28 January - 8 February, 2008 Madrid

Published:

CSN CONSEJO DE SEGURIDAD NUCLEAR

Integrated Regulatory Review Service (IRRS) to Spain

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Published:
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Presentation

This report marks the end of a long journey of work and cumulative effort by the Spanish Nuclear Safety Council that began over two years ago, when, at the proposal of the CSN, the Spanish government solicited an IRRS Mission (Integrated Regulatory Review Service) from the International Atomic Energy Agency (IAEA).

The mission of the CSN, assigned by the Spanish Parliament, is to protect the workers, the public, and the environment from the harmful effects of ionizing radiations by making sure that the nuclear and radioactive facilities are operated in a safe manner and establishing the preventive and performance means to deal with radiological emergencies, whatever their origins may be.

The CSN is a mature institution that has kept a vigilant watch over nuclear safety and radiological protection in our country since its founding in 1980, being the only national organisation competent on these duties. Nevertheless, the Council is should adapt itself to the changing rhythm and new demands of society. Because of this, and in an effort to continuously improve our mission, we invited the greatest world authority on the matter, the IAEA, to conduct an integral review of our regulatory system.

The IAEA is the Agency of the United Nations in charge of surveying the peaceful uses of ionizing radiations in fields such as energy production and health, and to disseminate its information among its Member States. To achieve this, the IAEA has established standards of nuclear safety and radiological protection, which can be used as basis to adopt national normative. These standards are the source of information to perform the missions of the Agency such as the IRRS.

At the Spanish regulatory body, we have realized that the evaluation of the IAEA, with respect to the application of its safety standards, would be a useful way of analyzing our progresses and detecting aspects that could be improved for the fulfilment of the functions of the CSN.

We also realized that this would be the best way to achieve one of the goals that the current Council had set: to carry out our work with the greatest possible degree of transparency, which would, without a doubt, be an advantage not only for the general public, but also for the companies that are regulated by the CSN.

Furthermore, keeping in mind that we are part of a global society, we see that it is vital for the sake of international cooperation to foster good practices in the scope of nuclear energy and radiological protection, as cooperation and the exchange of knowledge are indispensable in a world where technology and regulatory norms are dominant.

The IRRS missions are performed in several stages: a primary self-evaluation of the organization to be reviewed, a visit to the organization by a team of technical personnel from the IAEA, to explain the purpose and means, and the real IRRS mission, with the visit of an international team, with specialists in all the areas that will be analysed.

The evaluation of the Spanish Nuclear Safety Council had been full-scope, including for the first time security aspects.

Once the self-evaluation had been completed, a technical team of twenty-four specialists representing fifteen countries visited the CSN. For an intense two weeks, the Council shared the daily in and out workings of our regulatory system with the IRRS team. All the aspects related with the safety of nuclear plants and nuclear fuel cycle facilities, the security of radioactive sources, the safety and radiological protection in industrial and medical practices, the safety and security in the transport of radioactive materials, the management of radioactive waste (including spent fuel), the environmental protection and the emergencies preparedness underwent review and analysis. Legislative and governmental responsibilities were also object of analysis, as well as their relationship with the regulatory body.

As is evident from the report, an intensive and extensive examination was conducted, which, although having required a significant amount of energy, was, without a doubt, well worth the effort.

I can guarantee with full satisfaction that the results have proven to be very positive for our country. Numerous good practices have been identified in important areas of work, such as the technical competency of the Council's personnel and of the infrastructure necessary for the development of its labour, the legislative frame that guarantees the competencies of the Council and its necessary independence, the supervision of the nuclear plants through the Integrated System for NPPs Supervision and the advances in transparency and communication with the public, among other distinguished fields.

The IAEA has suggested some areas for us to work on in order to become more efficient in our functions. These are measures that we will incorporate without a doubt, as the objective of this review was nothing other than to continue to improve our work in order to offer the best results to our society.

In the name of the Spanish Nuclear Safety Council, I would like to thank all the companies, organizations and institutions for their collaboration, to recognize the IAEA team for a job completed with as much skill as enthusiasm, and to extend, once again, a hearty congratulation to the experts from the CSN for their professionalism and devotion.

All of you have made the findings of this report possible. Without a doubt, this report will result in the greater social credibility of the Council and a growth in the trust of the public regarding our regulatory practices, consolidating a management system based in the degree of quality and efficiency that puts us at the same level with the most advanced national regulatory systems in the world.

Carmen Martínez Ten
President of Spanish Nuclear Safety Council

NS/2008/01
ORIGINAL: English

IAEA
International Atomic Energy Agency

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

SPAIN

Madrid, Spain
28 January to 8 February 2008

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated regulatory review service IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaS SIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation; and (e) the International Physical Protection Advisory Service (IPPAS) that is conducted to review the effectiveness of State systems of physical protection and to provide advice and assistance to strengthen and enhance these systems.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste, transport safety and nuclear security, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety of radioactive sources, the safe management of radioactive waste, the safe transport of radioactive material and nuclear security. The IRRS is carried out by comparisons against IAEA regulatory safety standards and against international legal instruments and IAEA guidance on nuclear security with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and

control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and nuclear security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

- A balance between technical and policy discussions among senior regulators.
- Sharing of regulatory experiences.
- Harmonization of the regulatory approaches among Member States.
- Mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than 85 Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

The first IRRS missions were held in Romania and the United Kingdom in 2006. The first full scope mission was held in November 2006 in France. In March 2007, the French Nuclear Safety Authority (ASN) organized an international workshop in Paris, France, to disseminate the lessons learned from the first full scope IRRS mission, to share experiences from the 2006 missions and to provide information to Member States interested in availing of this service. The workshop, which was attended by more than 100

participants representing 35 countries, emphasized the importance of IRRS missions as a key tool in enhancing the effectiveness of a regulatory body and noted that such IRRS missions have begun a positive process for nuclear and radiation safety throughout the world.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and security guidance and the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety and security Conventions and Codes of Conduct, as well as the application of the IAEA safety standards and security guidance in order to prevent serious accidents and continuously improve global levels of safety.

INTEGRATED REGULATORY REVIEW SERVICE
(IRRS)
REPORT TO
THE GOVERNMENT OF SPAIN
Madrid, Spain

Mission date: 28 January to 8 February 2008

Regulatory body: CSN

Location: CSN headquarters, Madrid (Spain)

Regulated facilities and practices: *Nuclear power plants, fuel cycle facilities, medical and industrial sources, research applications, waste facilities, decommissioning and remediation, communication and public information.*

Organized by: International Atomic Energy Agency (IAEA)

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IAEA - 2008-02-06
Issue date: 2008-04-28

Foreword

The General Conference Resolution of September 2006 related to the measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: "Recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat's new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS."

At my opening speech of the fiftieth regular session of the General Conference in 2006, I stated that: "The Agency's safety review services use the IAEA Safety Standards as a reference point, and play an important part in evaluating their effectiveness. This year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS). This new service combines a number of previous services, on topics ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. The IRRS approach considers international regulatory issues and trends, and provides a balance between technical and policy discussions among senior regulators, to harmonize regulatory approaches and create mutual learning opportunities among regulators."

"A reduced scope IRRS was conducted for the United Kingdom Nuclear Installations inspectorate in March of this year. A full scope service will be conducted in France in November. The Agency has also received requests for IRRS missions from Australia, Canada, and Spain, and other Member States have expressed interest in having such missions in the near future. I would request all countries to take advantage of this service. I remain convinced that transparency and introspection are essential ingredients of an effective nuclear safety culture." (Statement to the Sixty-Second Regular Session of the United Nations General Assembly by IAEA Director General Mohamed ElBaradei. 29 October 2007.)

As the nuclear industry becomes increasingly international, IAEA Safety Standards are used as a reference point by an ever greater number of countries, and serve as a benchmark for IAEA safety review services. Last year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS), which combined previous services ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. IRRS missions have been conducted in France, Australia and Japan over the past year. This is contributing towards a more active exchange of knowledge among senior regulators, and promoting harmonized nuclear regulatory approaches worldwide.

Mohamed ElBaradei
IAEA Director General

The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

Contents

Executive summary

At the request of the Government of Spain, an international team of 23 experts in nuclear, radiation, transport and waste safety and nuclear security visited the Spanish Nuclear Safety Council (Consejo de Seguridad Nuclear CSN) from 28 January to 8 February 2008 to conduct a full scope Integrated Regulatory Review Service (IRRS) mission to review the CSN regulatory framework and its effectiveness. CSN is the only competent body in matters pertaining to nuclear safety and radiation protection in Spain and it has a key role with regard to nuclear security.

The purpose of this IRRS mission was to conduct a review of the CSN regulatory framework and regulatory activities apply to all regulated sources, facilities and activities, to review its regulatory effectiveness and to exchange information and experience in the areas covered by IRRS. The review was carried out by comparison against IAEA safety standards and security guidance and the relevant Conventions as the international benchmark for safety and security. It is expected that the IRRS mission will facilitate regulatory improvements in Spain and throughout the world from the knowledge gained and experiences shared by CSN and the IRRS reviewers and through the evaluation of the effectiveness of the CSN regulatory framework and its good practices.

The scope of the mission included sources, facilities and activities regulated by CSN: safety of nuclear power plants (PWR and BWR); safety of fuel cycle facilities; physical protection of nuclear installations; safety and security of radioactive sources; radiation safety in industrial practices; safety and security in the transport of radioactive material (limited to CSN's role); radioactive waste management (inducing spent fuel), decommissioning and remediation of contaminated sites; environmental surveillance; incident and emergency planning and preparedness.

Both regulatory technical and policy issues were addressed. The policy issues discussed were: risk informed approach, natural radiation, regulatory effectiveness and transparency and openness.

The IRRS Review Team consisted of 18 senior regulatory experts from 15 Member States, two observers, three staff members from the IAEA and an IAEA administrative assistant. The IRRS team carried out the review of CSN in all relevant areas: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities of the regulatory body, including the authorization process, review and assessment, inspection and enforcement and the development of regulations and guides; and special regulatory infrastructures.

The mission included a series of interviews and discussions with key personnel at CSN and at other organizations with a view to observing regulatory activities and the effectiveness of the system. Interviews and discussions took place with: staff at the Ministry of Industry, Tourism and Commerce; the Ministry of the Interior; and CIEMAT (Centro de Investigaciones Energéticas Medioambientales y Tecnológicas); with plant managers and staff of operating organizations of NPPs, with emphasis on nuclear and radiation safety and on physical protection; with staff at fuel cycle facilities; industrial facilities (accelerators/irradiators and industrial radiography facilities); medical facilities (for radiotherapy, nuclear medicine and diagnostic radiology); ENRESA (Empresa Nacional de Residuos Radiactivos) radioactive waste repository (El Cabril);

and decommissioning and remediation organizations including a mining site; and with staff carrying out an emergency response drill (Ascó NPP).

CSN supplied substantial documentation and a well prepared self-assessment, including an evaluation of the strengths of and proposed actions to improve the regulatory effectiveness of CSN. CSN also made available similar information of a confidential nature to the reviewers for the nuclear security module. The IRRS Review Team was impressed by the extensive preparation at all CSN staff levels. Throughout the review the administrative and logistical support was outstanding and the team was extended full cooperation in technical regulatory and policy discussions with CSN management and staff. The IRRS Review Team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue improving the effectiveness of regulatory controls.

These recommendations and suggestions are made to an organization that is seeking to improve its performance and many of them are related to areas in which CSN has already or is in the process of implementation a programme for change.

Particular strengths of CSN, its policy, its regulatory framework and its regulatory activities identified by the IRRS team were:

- A comprehensive legal infrastructure that includes all the relevant international conventions being in force; the law establishing CSN and associated laws providing CSN with the full range of regulatory and related functions and establishing CSN as the sole competent authority in nuclear safety and radiation protection and fully independent in making regulatory decisions; and a suite of supporting regulations, including binding regulations that may be made by CSN itself.

- Highly capable professional staff whose competence is well respected by licence holders, with a strong supporting infrastructure, including a very effective internal regulatory information and documentation system; detailed working processes and procedures; and a management system updated generally in accordance with international requirements.
- The commitment to and actions taken in recent times towards achieving effective transparency and communication with the public and parliament.
- The ongoing modernization of CSN's nuclear regulatory approaches by incorporating the use of probabilistic risk assessment in its licensing and the newly established reactor oversight approach (SISC) similar to the one used by the US-NRC.
- The effective collaboration between CSN and ENRESA in radioactive waste management strategy and programmes and the effective oversight and completion of decommissioning projects.
- The progress with implementation of the Code of Conduct on the Safety and Security of Radioactive Sources.
- The well trained emergency preparedness organization in place together with a very modern and well equipped emergency centre (SALEM).

- The effective collaboration between CSN and the Ministry of the Interior (MIR) in physical protection related activities and the effective use of regulatory and licensing activities to enhance physical security at nuclear facilities.

The report includes recommendations or suggestions where improvements are necessary or desirable to further enhance the legal and governmental infrastructure for radiation and nuclear safety and physical protection. The IRRS Review Team identifies some high priority issues where the team believes that consideration of these items may significantly enhance the overall performance of the regulatory system:

- Making careful judgements of priorities for meeting the ongoing improvements in CSN's current activities and for implementing the provisions of the new law, including upgrading of CSN's activities/role in the radiation protection of patients and the implementation of the advisory committee on transparency and public communication and international activities, taking into account the need to weigh various approaches to achieve transparency against the fundamental need for nuclear and radiation safety.
- Seeking to build greater flexibility and broader coverage into the recruitment of above base-level staff and non technical professionals to CSN, taking into account the need to cover the broad range of activities and future retirements of senior staff.
- Following the international good practice of mature regulatory bodies by establishing a technical advisory committee of experienced experts in the nuclear and radiation protection field. This committee would advise the technical directors on important issues like license renewals to give a second opinion for the decision makers. The IRRS team believes that such a technical committee could enhance the basis for its decision making and at the same time could improve the trustworthiness of CSN.
- Increasing CSN participation in national radioactive waste management programmes and encouragement of the development and communication of plans for the final disposal of spent fuel and HLW.
- Strengthening the oversight on human and organizational factors in all areas for which CSN is responsible to reflect the fact that the safety of nuclear and radiation facilities depends strongly on good safety culture as well as safety measures and robust design.
- Continuing to focus on ongoing efforts to strengthen CSN's activities in physical protection through collaboration with relevant governmental bodies on a forthcoming royal decree and related instructions and internal procedures.

The IRRS Review Team findings are summarized in Appendix V. There was a strong consensus among the IRRS Review Team that CSN and IAEA Member States have been improving the regulation of nuclear, radiation, transport and waste safety and nuclear security worldwide through IAEA regulatory review missions and services.

I. Introduction

At the request of the Government of Spain, an IAEA team consisting of eighteen experts and two observers from Member States, three staff members from the IAEA and an IAEA administrative assistant visited the Spanish Nuclear Safety Council (Consejo de Seguridad Nuclear - CSN), from 28 January to 8 February, 2008 to conduct a full scope Integrated Regulatory Review Service (IRRS) mission to review the CSN regulatory framework and its effectiveness. In September 2007, a preparatory mission had been carried out at CSN headquarters, Madrid to discuss the objective and purpose of the review as well as its scope in connection with all aspects of the work of CSN.

The areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; safety of radioactive sources; emergency preparedness; radioactive waste management, decommissioning, remediation; transport; emergency preparedness; the management system and public information and communication. For the first time the IRRS mission included a module on nuclear security to review the security of nuclear and radioactive material in use, storage and transport.

In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of the regulatory issues that may have international implications and assist in addressing specific technical issues relevant to the regulation of nuclear, radiation, radioactive waste and transport safety. Regulatory technical and policy issues were identified by CSN as a result of its self-assessment and considering insights resulting from the conclusions of the review meetings of the Convention on Nuclear Safety, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, international conferences and forums and previous IAEA safety review services.

Before the mission, CSN made available a collection of advance reference material for the team to review. This material consisted of a large number of legal, regulatory and internal documents, in particular the report on self-assessment including the IAEA questionnaire. During the mission the team performed a systematic review of all topics using the report on self-assessment, the advance reference material, interviews with CSN staff, other involved organizations and direct observation of their working practices during inspections carried out by CSN.

IRRS activities took place mainly at the CSN headquarters, Madrid. The mission included a series of interviews and discussions with key personnel at CSN and at other organizations with a view to observing regulatory activities and the effectiveness of the system.

The IRRS team responsible for the module on nuclear security reviewed confidential documents relating to nuclear security, observed CSN inspections at Confrenetes NPP and held interviews with representatives of the Ministry of Industry, Tourism and Commerce and MIR responsible for nuclear security.

II. Objective and scope

The purpose of the mission was to conduct a full scope IRRS mission to review the Spanish legal and governmental infrastructure for nuclear, radiation, radioactive waste and transport safety and the physical protection of nuclear installations and the effectiveness of the Spanish regulatory body (CSN) and to exchange information and experience among CSN and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among senior regulators.

The key objectives of this mission were to enhance nuclear and radiation safety and nuclear security by:

- Providing Spain (CSN and governmental authorities) with a review of their regulatory technical and policy issues relating to nuclear and radiation safety and the physical protection of nuclear installations.
- Providing Spain (CSN and governmental authorities) with an objective evaluation of their nuclear and radiation safety regulatory activities with respect to international safety standards.
- Contributing to the harmonization of regulatory approaches among Member States.
- Promoting sharing of experience and exchange of lessons learnt.
- Providing key staff (CSN and governmental authorities) with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field.
- Providing Spain (CSN and governmental authorities) with recommendations and suggestions for improvement.
- Providing other States with information regarding good practices identified in the course of the review.
- Providing reviewers from States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field.
- Providing CSN through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against international safety standards.
- Providing CSN with a confidential review of Spain's national nuclear security regime and the evaluation of CSN regulatory activities against international instruments and guidance covering nuclear security.

III. Basis for the review

A) Preparatory word and IAEA review team

At the request of the Spanish government authorities, an IAEA team of three IAEA staff members visited the CSN in February 2007 to conduct a preparatory mission for the Integrated Regulatory Review Service (IRRS). The mission focused on:

- Discussing and confirming the subject areas to be reviewed and the material that the regulatory body needs to provide.
- Providing all applicable IRRS questionnaires and explaining the importance of the regulatory preparation for the self-assessment to be made by the CSN prior to the conduct of the IRRS mission.
- Informing the CSN how the IRRS review process works, as this is the first full-scope IRRS including security aspects mission ever organized.
- Explaining the roles and responsibilities of the IRRS team members and the way they should interact with the regulatory body, other organizations and facility representatives.
- Explaining the role of the liaison officer and the counterparts before and during the review.
- Agreeing an outline schedule for the mission and agree to logistical aspects.
- Explaining IAEA policies, e.g. funding, contact with the mass media.

The IAEA staff had extensive discussions with the senior management of CSN represented by the CSN Chairperson, Ms. Carmen Martinez Ten and the four Commissioners: Mr. A. Colino Martinez, Mr. J. Barcelo, Mr. L. Gámir and Mr. F. Fernandez Moreno; the Liaison Officers for the IRRS mission: Ms. Isabel Mellado, Director of Nuclear Safety Department, Mr. J. C. Lentijo Director of Radiation Protection Department, and Mr. Alfredo de los Reyes, Head of International Affairs Division attended all the discussions of the preparatory mission.

As a result of these discussions, the scope of the mission was confirmed to cover the full spectrum of all regulated facilities, activities and practices under CSN including the nuclear security of nuclear and radioactive material. The main organizational and logistical issues related to the conduct of the mission were also discussed. In addition, it was agreed that the following documentation will be provided by beginning of November 2007 in order to be discussed in a pre-mission: Self-Assessment (completed questionnaires; detailed analysis and draft Action Plan); National reports of Nuclear Safety Convention and Joint Convention together with related questions and answers; Annual reports to the Parliament; Relevant legislation and regulations (minimum: summaries in English); CSN policy on communication and information; Management System documentation describing relevant policy and procedures; Lesson learned from incidents (Vandellos II); and Regulatory strategy (present and future).

B) References for the review

An IAEA team of five experts consisting of two external experts and three staff members from the IAEA visited the CSN in September 2007 to conduct a preparatory mission for the Integrated Regulatory Review

Service (IRRS). The objective of the preparatory mission was to determine the issues to be discussed in the main IRRS review, to ensure that the main mission would be carried out efficiently and, in particular, to discuss Spain's self-assessment and new technical and policy issues to be reviewed during the main mission.

The preparatory work for the preparatory mission was carried out by the appointed Team Leader Mr. Ulrich Schmocker, Director of the Swiss Federal Nuclear Safety Inspectorate (HSK), the appointed Deputy Team Leader, John Loy, Chief Executive Officer of the Australian Radiation Protection & Nuclear Safety Agency (ARPANSA) and the IRRS IAEA Team Coordinator Gustavo Caruso, NSNI/IAEA, the IRRS Deputy Team Coordinator, Khammar Mrabit, NSRW/IAEA and the IAEA Nuclear Security Team Coordinator Miroslav Gregoric, NSNS/IAEA.

During the preparatory phase, a number of documents of the advance reference material (ARM) that had been received from CSN were distributed to the experts. These documents underwent a preliminary review, which was conducted in a systematic way, based on the IRRS modules and using the appropriate review criteria (IAEA safety standards and security guidance). The main documents provided by CSN as part of the ARM and which were reviewed by the experts in preparation for the preparatory mission are included in Appendix VI. The most relevant IAEA safety standards used as review criteria are: GS-R-1, *Safety Requirements on Legal and Governmental Infrastructure*; GS-R-2 *Safety Requirements on Preparedness and Response for a Nuclear or Radiological Emergency*; GS-R-3, *Safety Requirements on The Management System for Facilities and Activities; the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources* (the BSS); TS-R-1, *Regulations for the Safe Transport of Radioactive Material; and the Code of Conduct for Safety and Security of Radioactive Sources*. The most relevant documents used in the nuclear security review were the *Convention on the Physical Protection of Nuclear Material* as amended, GC-INFCIRC/225/Rev4 on the *Physical Protection of Nuclear Material and Nuclear Facilities*.

The preparatory mission consisted of a review of all eight IRRS modules identified in the mission's scope, with the objectives of:

- Identifying main issues to be focused on by the main mission;
- Clarifying the answers provided to the IRRS questionnaires
- Identifying additional information and material to be prepared for the main mission.

Discussing the team composition, that is senior regulators from Member States and observers, to be involved in the review in accordance to the scope as well as logistics including meeting spaces and work spaces, counterpart identification, lodging and transportation to accommodate site visits and observations.

The team carried out discussions on regulatory technical and policy issues with the senior management of the CSN represented by the CSN Chairperson, the four Commissioners, the Liaison Officers for the IRRS mission, the Director of Nuclear Safety, the Director of Radiation Protection and the Head of Presidency Technical Cabinet.

In accordance with the request from CSN, and taking into account the scope as indicated above, it was agreed that the IAEA review team would comprise 18 external experts and 2 observers from 17 Member States (see Appendix I). The working areas and the CSN counterparts were distributed according to Appendix IV.

During the preparatory period all documents of the advance reference material (ARM) were sent to the IAEA and distributed to the experts. A significant amount of work was carried out by the reviewers and by the IAEA staff before the main review in order to prepare the initial impressions about the ARM, to review the answers to the questionnaire sent by CSN, to prepare for the interviews and direct observations at the sites and to identify additional relevant material necessary to review during the mission.

C) Conduct of the review

The main reference documents provided by CSN for the review mission are listed in Appendix VI. The most relevant IAEA safety standards and security guidance and other reference documents used for the review are listed in Appendix VII.

D) Conduct of the review

An opening team meeting was conducted on 27th January 2008 at the CSN Headquarters by the IRRS Team Leader, the IRRS IAEA Team Coordinator, IRRS IAEA Deputy Team Coordinator and the IAEA Nuclear Security Team Coordinator to discuss the specifics of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. The opening remarks were given by Commissioner J. Barcelo and the Liaison Officer and the Deputy Liaison Officer were present at the opening team meeting, in accordance with the IRRS guidelines. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 28th January 2008, with the participation of CSN senior management. Opening remarks were made by Ms. Carmen Martinez Ten, CSN Chairperson, Mr. Julio. Barcelo, CSN Commissioner, the IRRS Team Leader and the IRRS Deputy Team Leader.

During the mission, a systematic review was conducted for all the review areas with the objective of providing CSN with recommendations and suggestions as well as of identifying good practices. The review was conducted through meetings, interviews and discussions as stated in the previous sections, visits to relevant organizations, assessment of the ARM, and direct observations regarding the national practices and activities.

The team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday, 8th February 2008, with the CSN authorities: the CSN Chairperson, the four Commissioners, representatives of the Ministry of Industry, Tourism and Commerce (MITyC) Mr. Javier Arana, the Liaison Officers, the General Secretary of CSN attended the meeting as well as department heads, division heads, section heads, technical staff and support staff.

The opening remarks of the exit meeting were presented by Ms. Carmen Martinez Ten and Mr. Julio Barcelo. The results of the IRRS mission were presented by Mr. Schmocker, Mr. Loy, Mr. Reyes and Mr. Price. The closing remarks were made by Mr. Philippe Jamet, Director of the Division of Nuclear Installation Safety.

The draft technical notes of the IRRS mission and the confidential report on the IRRS module on nuclear security were handed over to CSN at the end of the exit meeting.

1. Legislative and governmental responsibilities

1.1. General

Legislative and statutory framework

At the highest level (subject to the Spanish Constitution), the principal **nuclear laws** that establish the framework for regulation of the safety of facilities and activities in Spain are:

- The Law establishing the Council on Nuclear Safety (CNS) (Law 15/1980 as amended in 1999 and recently by Law 33/2007).
- The Nuclear Energy Law (Law 25/1964 as amended in 1997, by Law 24/2005 and also by Law 33/2007).

These **nuclear laws** are supported in their application by **general administrative laws**. In addition, the Law on Fees and Public Prices for Services Rendered by the Nuclear Safety Council is important in establishing the funding for the Council independent of the Government budget.

The Spanish Government also applies the provisions of international conventions in effect that it has ratified and formally notified. Spain has ratified all the existing international conventions affecting radiation protection and nuclear safety.

The team undertook a comparative analysis to understand the current state of the Law in the light of the amendments to the **nuclear laws** adopted in 2007. These amendments include:

- Clarifications and additions to the functions of the CSN, notably the addition of physical protection to the matters on which it provides reports to the Ministry of Industry, Tourism and Commerce (MITYC) and requiring it to collaborate with competent authorities with respect to the radiation protection of patients.
- Strengthening and clarification of the appointment provisions for members of the Council and high level positions and establishing that the Council is a collegiate body.
- Applying explicitly requirements that the CSN provide information to the public and the Parliament.
- The application and operation of whistle blowing provisions.
- The establishment of an Advisory Committee on communications and transparency.
- An updated structure for enforcement and application of penalties.

Below the level of the laws and the conventions, there are **Regulations** (Royal Decrees) concerning nuclear safety and radiation protection and related subjects made by the Government under the nuclear laws. The most significant relevant regulations are:

- Regulations on Nuclear and Radiation Facilities (RINR), which expand on the procedures for granting authorizations to installations and staff. These Regulations are currently being updated (modification already published on 18th February 2008).
- Regulations on Health Protection Against Ionising Radiations, which implement the European basic safety standards.
- Regulations on Installation and use of X-Ray Devices for Medical Diagnosis. These Regulations are also in the process of being updated.
- Regulations on Physical Protection of Nuclear Material (currently being updated to reflect the revised CPPNM).
- Regulations on Control of High Activity Sealed Radioactive Sources and Orphan Sources, which implement the relevant EU Directive.

The Nuclear Safety Council law also empowers the CSN to make and issue **CSN Instructions** – these are technical rules made by the CSN that are legally binding on licence holders, when they are notified or published in the Boletín Oficial del Estado (BOE). There are currently 18 such CSN Instructions in effect. These CSN Instructions are made after appropriate consultation with relevant stakeholders, but the process is simpler and quicker than the making of Royal Decrees. The CSN must notify the Parliament before adopting an Instruction.

Authorizations of facilities and practices are issued by the MITYC following report by the CSN. Authorisations include conditions as required by CSN.

Complementary Technical Instructions may also be issued by the CSN to licence holders and are binding on them. These reinforce, develop or complement the limits and conditions of the operating authorization.

The CSN is also empowered to issue **Circulars** and **Safety Guides** providing guidance on meeting the regulatory requirements.

The IRRS team assessed this legislative and regulatory framework as being comprehensive, with an appropriate range of instruments allowing for flexible and effective legal regime. It certainly fulfils the requirements of GS-R-1 2.2[1].

Establishment of an effectively independent regulatory body

The Nuclear Safety Council Law (15/1980 as amended by 33/2007) establishes the CSN as *"the only competent body in matters pertaining to nuclear safety and radiation protection"*. The MITYC is charged with granting the necessary authorizations for construction, operation, modifications, transportation, dismantling and decommissioning of the facilities, but it can do so with regard to radiation protection and nuclear safety only consistent with a report of the CSN. This arrangement meets the criteria laid down in para 2.5 of GS-R-1 concerning the granting of authorizations by bodies not meeting the requirement of independence,

in that the MITYC has no legal capacity to do other than act consistently with the report of the CSN as regards nuclear safety and radiation protection.

The IRRS Team closely inquired into the *de jure* and *de facto* independence of the CSN from the MITYC, noting also that it is the Minister for Industry, Tourism and Commerce that brings forward nominations for appointments as members of the Commission. On the basis of the CSN self assessment and interviews with CSN and MITYC, the team noted:

- The very clear provisions of the Nuclear Safety Council Law that mean that the MITYC can only accept what is put forward in the report of the CSN with respect to radiation protection and nuclear safety
- The similarly clear provisions of the Law to the effect that the CSN is an independent agency and the sole competent authority in Spain with respect to radiation protection and nuclear safety
- The involvement of the Parliament on the basis of a 3/5 majority vote to approve nominations of persons for membership of the Council and the term of a Commissioner being six years
- The nuclear regulatory culture and tradition established which accepts and supports the independent role of the CSN.

The IRRS Team agrees that the Spanish arrangements meet the requirements of 2.2[2] of GS-R-1.

It is, of course, possible to envisage a system in which the CSN would be the authorizing body in relation to radiation protection and nuclear safety, with authorizations relating to other matters being undertaken by the relevant Ministries. Whether this would be more or less efficient is purely a matter for judgement by Spain in the context of its Governmental arrangements.

Regulatory body - assigned responsibilities, authority, and resources

As noted above, the formal responsibility for authorization of facilities and activities resides with the MITYC, rather than the CSN. However, the provisions of the Nuclear Safety Council Law (notably article 2(b)) make it clear that MITYC has no independent authority in relation to authorization relating to radiation protection and nuclear safety and the CSN has the *de facto* power of authorization.

Article 2 of the Nuclear Safety Council Law clearly gives responsibility for regulatory review and assessment; inspection; and the establishment of safety principles, criteria, regulations and guides to the CSN.

Enforcement is a shared responsibility between CSN and the MITYC. The CSN is empowered, for minor infringements, to issue a warning to a licensee and require corrective procedures; it may issue civil penalties that are defined fractions of the full penalty for an infringement; and it may propose the initiating of disciplinary proceedings to the MITYC or the autonomous community where relevant.

The power and authority of the CSN rests on the Law Establishing the Nuclear Safety Council, which states that CSN is the only competent body in matters pertaining to nuclear safety and radiation protection.

The bulk of the financial resources available to the CSN (around 90%) flow from fees established under the Law on Fees and Public Prices for Services Rendered by the Nuclear Safety Council - Law 14/1999. That Law establishes fixed fees for operating plants and facilities and a determined means of calculating the fees for applications for authorizations. The team was advised that the level of fees is adjusted annually through the Government Budget process in accordance with a cost index.

While this is a basically satisfactory means of financing the regulatory activities of the CSN – and re-affirms its independence – a number of other countries have found that it is useful with regard to regulation of operations to levy a basic fee and then additional fees or charges based upon the amount of regulatory activity generated by the installation or facility. This builds in a price signal to operators that good regulatory performance results in lower costs and vice versa.

The overall financial resources available to the CSN to carry out its regulatory tasks appear to be adequate. The team noted that the recently revised law imposes large demands on the CSN to implement an extensive agenda of transparency, accountability and openness that, while commendable, will require the commitment of significant technical resources. The team was advised during its visit that the CSN has authorised the establishment of 20 new technical staffing positions, in part as a response to the agenda set by the revised law.

The staffing resources available to the CSN are professionally first rate – this is confirmed by the interaction of team members with their CSN counterparts and in external contacts made by the team with licence holders. There seems to be no difficulty in recruiting new 'base-level' staff of high quality.

The CSN activities in environmental monitoring and emergency management are funded directly from the Government Budget.

There are several functions of CSN derived from Article 2 of the CSN Law that are "non regulatory". These include:

- Collaborating with the competent authorities in the setting of criteria that off-site emergency plans, physical protection plans and transportation plans must meet.
- Coordinating radiation and nuclear safety arrangements in emergency response situations.
- Collaborating with competent authorities in the radiation protection of patients (new function) and with regard to the health of exposed workers.
- To inform the MITYC on the activities and activity concentrations of materials that constitute the various classifications of radioactive wastes.

The team was of the view that these and other similar functions are clearly not in conflict with the regulatory functions of the CSN.

Spain is a party to the Paris and Brussels Conventions on liability for nuclear damage.

The Law on Nuclear Energy stipulates that "any operator of a nuclear facility or any other facility that produces or works with radioactive materials or has devices that may generate ionising radiations to carry out any nuclear activity, in addition to obtaining the preliminary authorization, shall set up a coverage of the risks that may occur in relation to its liability derived from nuclear accidents." Radiation facilities of lower hazard category are exempted from the requirement to establish risk cover.

In the case of nuclear facilities, the coverage required in relation to operator liability for nuclear damage is 700 million euros. However, the MITYC may establish another limit, not lower than 30 million euros, when dealing with nuclear substance transports or any other activity the risk of which, in the opinion of the CSN, does not require a higher coverage.

A draft for a Law on Liability for Nuclear Damage is being developed. This will deal with the amendments of the Paris Convention and address particularly the limits of liability for other than nuclear facilities.

Responsibility for technological infrastructure in radiation protection and nuclear safety is not mandated by the current legislation. CSN is a technically capable body with the ability and the resources to contract for external technical support, including through the CIEMAT.

Article 36 of the Nuclear Energy Law was amended Law 33/2007 to include an extended description of the responsibilities of the operator for safety. These provisions are worth quoting:

Licensees of nuclear or radiation facilities or of ionising radiations related activities shall be responsible for their safety.

Nuclear and radiation facilities, and radioactive mineral operations, shall develop their activities in a way such that required safety conditions are maintained, *taking the measures needed as to prevent nuclear and radiological accidents, as well as the measures to mitigate their consequences, were the latter to happen; and shall comply with as many provisions as stipulated by the corresponding regulations, as regards nuclear safety and ionising radiations.*

Said provisions shall make reference both to working conditions and to the hazards entailed by ionising radiations on workers professionally dedicated to nuclear activities, as well as other people, things and the environment, that might result affected *by such radiations and activities.*

Likewise, competent authorities and licensees shall adopt the preventive and protective measures required to maintain appropriate physical safety conditions in these facilities.

The organizations responsible for managing nuclear and radiation facilities shall have the appropriate human, technical and economical resources available in order to maintain safety conditions, and shall incorporate the basic safety management principles.

Nuclear and radiation facility staff shall comply with suitability requirements established in the *corresponding regulation, and shall be required to pass the medical tests or any other test established by regulations in order to* verify *said suitability.*

A Chief Operating Officer *shall be appointed at each nuclear facility who* satisfies *the conditions established by regulations, and who shall be responsible for the supervision of all facility usage and operations, being technically responsible of its performance.*

The Chief Operating Officer *shall have the authority to suspend facility operations whenever he/she deems it as appropriate or necessary.*

This full statement of operator responsibility – drawn from the IAEA Safety Fundamentals – is exemplary being contained within the overall nuclear energy law. This gives the description of the fundamental operator responsibilities a higher status than their being included in regulations or conditions of authorization.

1.2. Legislative

Legislative requirements

The Nuclear Energy Law as amended in 2007 has the following statement of purpose:

The purpose of this law is to establish the legal framework *for the development and implementation of peaceful nuclear power and ionising radiations applications in Spain, in a way such that people, things and the environment are properly protected.*

This statement is consistent with the fundamental safety objective stated in the IAEA Safety Fundamentals SF-1 'to protect people and the environment from harmful effects of ionizing radiation'.

The RINR defines the "nuclear installations" that are required to obtain authorization under the legislation. The same Regulations define "radioactive installations" and also provide defined exemptions from the generic definitions. Exclusion is dealt with in the Regulations on Health Protection against Ionizing Radiation.

The RINR establishes authorization and describes the processes and requirements for nuclear installations, radioactive installations, certain personnel of those installations and service providers. The process for authorization is described in section 4.1 of the Report.

Drawing on the CSN self assessment, each sub-paragraph of 2.6 was traced to a power or authority for the CSN derived from the CSN Law or at the level of Royal Decree, principally the RINR.

The procedure for the cessation of the operations and decommissioning of the facilities is specifically regulated in the RINR.

All resolutions from any administrative body in Spain are subject to the general administrative appeal system established under the Law on the Legal Regime System of Public Administrations and Common Administrative Procedure (Appeal to a superior court, Appeal for reversal, Extraordinary Appeal for Review).

Moreover, once the administrative procedures are completed and the resolution becomes definitive, a matter may be administratively appealed before the CSN itself, and subsequently the definitive administrative resolution may be tried by the Courts of Justice.

The same is true for the resolutions passed by the MITYC regarding a matter, which could be administratively appealed before the Ministry itself and subsequently before the Contentious Administrative Appeals Courts.

Article 12.1 (h) of the RINR requires that any change in the ownership (the title holder) of a nuclear installation requires authorization. Article 36 requires authorisation for change of ownership for radiation facilities of the nuclear fuel cycle. In the case of medical/industrial radiation facilities, a change of authorisation is also required.

Art. 13 of the Royal Decree 1157/1982 approving the Statute of the Nuclear Safety Council, authorizes the CSN to set up Advisory Committees for the study of matters of its competence. The Council has, however, chosen not to establish any such technical advisory Committee(s).

The new CSN Law of 2007 requires the establishment of an advisory committee for public information and involvement. This is discussed below with respect to GS-R-1 para 2.4(16).

The Law establishing the CSN indicates that one of the functions of the CSN is to establish and conduct the follow-up of the research plans as regards nuclear safety and radiation protection. The R&D Office within CSN oversees this function.

The 2007 amendments to the CSN Law also updated the provisions applying to responsibilities and obligations for financial provision for radioactive waste management and decommissioning. This is further considered in Chapter 8.

The 2007 amendment to the Nuclear Laws sets out a comprehensive range of offences and accompanying penalties.

In accordance with the Spanish Constitution, the international treaties signed and ratified by Spain are fully binding after formal notification, as they are part of the Spanish legal system.

The 2007 amendments to the Law establishing CSN state that;

> *The information access and public involvement rights in relation to Council competences referring to nuclear safety and radiation protection, shall be governed by the provisions of Law 27/2006, of 18th of July, regulating information access rights, rights of public participation and rights to recourse to justice in environmental issues.*

The Law 27/2006 establishes the rights of access to information, public participation and access to justice on environmental matters. The Law broadens the obligations on public authorities to make public relevant information on environmental matters and to provide easy access to information requested by concerned (broadly defined) people.

The 2007 CSN Law goes on to set out requirements for the CSN to operate transparently. There are requirements for public information especially with regard to events and incidents; the provision of information about Council decisions; public participation in the development of instructions and guides, particularly by making use of the website; and promotion and participation in public information forums in areas surrounding nuclear facilities.

The CSN has responded to this requirement by publishing in advanced important documents of its regulatory activities on its website including the minutes of meetings of the Council, reports on safety assessments, event reports submitted to the Council following its recently issued Instruction on event reporting, and inspection reports.

The Law also mandates the establishment of an Advisory Committee with a defined membership structure that is intended to advise the CSN on how to increase transparency, public information, access and involvement in CSN's activities. The CSN is working to establish this Advisory Committee.

The team considered the matter of transparency and public communication in some detail. It was the subject of policy discussions with counterparts. During that discussion, the CSN emphasised the importance it placed on website publication of CSN plenary meeting minutes, event reports, the reports from the new oversight process, and inspection reports. It was emphasised that the particular operators were informed in advance prior the reports being posted on the website. The IRRS team explored with counterparts, the implementation of full transparency on the one hand, which is achieved through having all information available and through periodic reporting and, on the other hand, effective public communication. For example, the web publication of complete inspection reports is effective transparency, but in fact may not achieve effective public communication, because of their detail and technical complexity.

The team strongly supports the commitment to transparency and public communication as being of vital importance, noting that there have been some difficulties of communication and perception that have arisen in the past. The team acknowledges the CSN's particular commitment to establish and maintain a flow of information to the public and its use of the CSN website to give direct access to many regulatory documents.

In implementing the ongoing commitment to transparency, in which the work of the to-beestablished Advisory Committee will be central, the team would draw attention to the need to carefully weigh differing approaches to achieve the desired goal of transparency and public communication against the fundamental need for nuclear and radiation safety. There are two broad aspects to this balancing: first, the resources committed to supporting transparency and public communication are derived from the total resources committed by the regulator and operator to achieving safety – transparency measures need to take into account efficiency; second, there may be unintended consequences of certain transparency measures that end up working against safety – for example, an operator might seek to avoid having to report a 20% power reduction by not reducing power in circumstances where such a reduction in fact limits radiation doses to the workers.

According to the RINR, the CSN has the authority to send, directly to the license holders, complementary technical instructions for ensuring that the safety conditions and requirements are being maintained, and for the better fulfilment of the requirements established in the corresponding authorizations.

According to the proposed revision to this Regulation (article 8.3) the licence holder shall look after the continuous improvement of the nuclear safety and radiation protection conditions of its facility. For that purpose, the licence holder must analyse the best existing techniques and practices in accordance with the requirements that the CSN establishes and shall implement those that are technically and economically viable, reporting to the CSN on all these matters.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 § 2.2[4] states that *the regulatory body shall be provided with adequate power and authority, and it shall be ensured that it has adequate* staffing *and* financial *resources to discharge its assigned responsibilities*

S1 **Suggestion**: The CSN should consider, in line with the practice adopted in other countries, whether to propose a change in the Law on Fees and Public Prices that would apply a base annual fee and charges for regulatory activities generated by licence holders so as to establish a 'price signal' for operators.

(1) **BASIS**: GS-R-1 § 2.3 states that *the prime responsibility for safety shall be assigned to the operator*

(2) **BASIS**: SF-1 Principle 1 *The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.*

G1 **Good practice**: The detailed statement of operator responsibility now established in the Nuclear Energy Law by the 2007 amendments.

(1) **BASIS**: GS-R-1 § 2.4 [16] states that *the legislation shall* define *how the public and other bodies are involved in the regulatory process.*

S2 **Suggestion**: In implementing the new legal provisions for the operation of the advisory committee on transparency and communications, the potential for there to be unintended adverse impacts of transparency and communications on safety should be carefully considered by CSN and debated with the advisory committee.

2. Responsibilities and functions of the regulatory bodi

2.1. General

Regulatory body - fulfilling statutory obligations

In addition to the regulations established through Royal Decrees, the CSN has established a comprehensive range of regulations, supported by safety guides and management procedures for taking regulatory actions. These are further described in chapter 4.3 on development of regulations and guides and chapter 9 on the management system.

The CSN has established a detailed and comprehensive process for review and assessment of submissions from operators prior to authorization, for modifications and periodically. These processes are consistent with the RINR. The processes for review and assessment are considered in chapter 4.2.

The authorization process established and operated by the CSN is well defined in terms of the matters covered by 3.2[3](i-x). This is described in detail in chapter 4.1.

CSN carries out regulatory inspections. There is a detailed inspection planning process and in the case of the NPPs there are two resident inspectors. There is a graduated range of enforcement powers detailed in the law and applied by CSN and, where appropriate, by the MITYC or the autonomous communities. The issues of inspection and enforcement are discussed in chapter 4.4.

Regulatory body – discharging its main responsibilities

The CSN has established Management Procedures about dealing with applications relevant to its functions. These are assessed as a part of the overall management system in chapter 9.

There is a structure for changing conditions of authorization – this is envisaged in the RINR and licensees are required to submit applications for authorization of modifications if these change the licensing basis for the facility. CSN may propose changing conditions of authorization to the MITYC and, where appropriate, may issue complementary technical instructions that expand the conditions of the license.

The CSN has established a number of Safety Guides on safety assessment and also published relevant information on its website. This matter is further discussed in chapter 4.2 on review and assessment.

There are internal CSN procedures for the protection of proprietary information.

There are Management Procedures that require that any refusal report includes the technical reasons and justifications for such refusal. Such reports are available publicly.

The CSN organises its responsibilities to communicate with other competent governmental bodies – including the Parliament, other relevant Ministries, the autonomous communities – and with international organizations and the public through areas located within the Technical Cabinet of the President.

The CSN provides an annual report to the Parliament that contains a description of its activities with respect to facilities and activities and an overall report on whether licensees have met requirements.

Each operating licence includes a condition that requires the analysis of both its own and other facilities' experience. The RINR requires that each nuclear installation provide an annual report that includes a description of operating experience. The analysis and dissemination of operating experience feedback is discussed in Chapter 4.2.

Article 72 of the RINR requires all licence holders to file documents and registers required under the RINR and other provisions and the authorization for set time periods. The specific provisions are included in the Quality Assurance Manual which forms part of the licensing basis for an installation – there are safety Guides available on quality assurance documentation for nuclear installations and radiation facilities.

The regulations applicable to NPPs, spent fuel, radioactive waste and dismantling are currently being reviewed within the framework of the WENRA project. The CSN analyses the applicability in Spain of all requirements that the IAEA issues. Licensees are required to send an annual report analysing the applicability of new regulations issued in the country of origin of the project.

The requirements for safety re-assessment and periodic safety review are set out in the conditions of licence. The requirements for specific installations are expanded upon in meetings with the operators as the time for periodic safety review approaches. A detailed discussion of this requirement is at Chapter 4.1.

The CSN ensures that the Government and Parliament are advised of matters related to the safety of facilities and activities through its annual report and other mechanisms coordinated through the Technical Cabinet of the President.

The CSN has a comprehensive set of arrangements that it undertakes directly or that it sets out criteria for assuring the competence of relevant personnel. This issue is covered further in Chapter 4.

This confirmation – the *raison* d'etre of a regulatory body – is reported on principally through the Annual report of CSN, which makes an overall assessment against each of the categories of installation and activity. In doing so, the CSN draws on an extensive range of measured safety indicators of nuclear installations.

Regulatory body – cooperation with other relevant authorities

(1) Environmental protection

On the basis of its competence as defined in the CSN Law, CSN provides advice with regard to radiation protection and nuclear safety to the relevant Ministry in the development of relevant environmental impact assessments.

(2) Public and occupational health

There is no role in the law for CSN in this area, but it advises relevant authorities in the area of its competence.

(3) Emergency planning and preparedness

The CSN has a direct and significant role in emergency planning and preparedness, interacting with other relevant authorities and the governments of the autonomous communities. This issue is assessed in detail in Chapter 7.

(4) Radioactive waste management

This is a central function of the CSN and is assessed in detail in Chapter 8.

(5) Public liability

CSN has no role in this area.

(6) Physical protection and safeguards

CSN's functions with regard to physical protection are assessed in the accompanying report on physical protection. The CSN has no role in administering or advising on safeguards.

(7) Water use and consumption of food

The CSN collaborates with health authorities in everything related to the admissible radioactive contents for water or food consumption.

(8) Land use and planning

The CSN collaborates with the competent authorities, proposing radiological criteria for the use of land that contains or has been polluted with radioactive materials and for the clearance of sites where practices that might have caused modifications in the radiological conditions of the land (during operation, dismantling or decommissioning) have taken place.

When it is necessary to establish use restrictions on radiologically polluted land, the CSN proposes the restrictions and collaborates with the competent authorities for their effective implementation and to monitor their maintenance through time.

(9) Safety in the transport of dangerous goods

This is a clear activity of the CSN in which it collaborates with relevant bodies and it is assessed in Chapter 6.

Regulatory body – additional functions

(1) Independent radiological monitoring in and around nuclear facilities

In response to its responsibilities under the CSN Law, the CSN contracts with CIEMAT to undertake environmental monitoring around the sites of nuclear facilities. The operators are also required to undertake their own monitoring.

(2) Independent testing and quality control measurements

The CSN does not carry out such functions.

(3) Safety related R&D in support of its regulatory functions

The CSN does support the undertaking of relevant R&D. this is co-ordinated through the Office of R&D, which is part of the Secretary General's area. Issues of conflict of interest do not arise and the CSN takes care to ensure that it does not undertake R&D that is properly to be performed by the operator(s).

(4) Providing personnel monitoring services and conducting medical examinations

The CSN does not undertake these functions.

(5) Monitoring of nuclear non-proliferation

The CSN does not undertake this function.

(6) Regulatory control of industrial safety

The CSN does not undertake this function.

3. Organization ot the regulatory bodi

3.1. General organization

The Nuclear Safety Council (CSN) was established by Law 15 of April 22, 1980. it was amended by law 33 of November 7, 2007. The CSN is now organized as described below. (see also appendix VIII for an organizational chart).

The president of the Consejo heads the CSN. The Secretary General is responsible for the day-to-day management of the CSN. The president and commissioners are nominated by the Ministry of Industry, Tourism and Commerce (MYTIC) and agree to by Parliament. A legal organization, personnel administration and information systems also reports to the Secretary General.

The CSN is divided into two General Directorates. The directorate of Nuclear Safety and the Directorate of Radiological Protection. The Secretary General, the Directors of the Nuclear Safety and Radiation Protection are positions agreed to by the Government after the Consejo informs the Ministry of their nominations.

A Technical Cabinet supports the office of the President. It includes personnel in International Relations, Communications, Government relations and document publication.

The technical Directorates uses a matrix organization in which technical experts provide their expert advice to distinct facilities projects. As result of high demand for the use of experts in risk assessment, operating experience and human factors CSN is considering enhancing this expertise by making organizational changes and adding additional experts.

As a result of new facilities being proposed such as the neutron spallation source and increase demand in the area of security international relations and law 33/2007 radiation protection of patients and communications, CSN resources balance will be challenged. As new technical positions are approved for CSN it needs to consider present and forthcoming skills needed.

Technical support organization (TSO)

In some countries, Regulatory Bodies may be relatively small but they are technically supported by other organizations (TSO). Such a difference is not a problem if all regulatory decisions are made independently, based on sound technical knowledge.

In the case of Spain, CSN, the regulator is mostly self supporting for its technical knowledge. CSN's technical knowledge is also supplemented by public organizations, private engineering organizations and consulting companies.

Among the public organizations used, Ciemat, (Centro de Investigaciones Energeticas Medioambientales y Technologicas) is the preeminent choice. With it roots in the 1950s Ciemat has extensive technical

knowledge and research facilities which are available and use by CSN to enhance their technical capabilities. CSN is sensitive to conflict of interest situations when external organizations are used to supplement their staff.

3.2. Staffing and training

Staffing

CSN has currently a total of 453 employees. The mission concluded that the existing staff numbers plus 20 additional technical positions recently approved by the Ministry seem to be in keeping with the actual missions of the CSN, but noting that this doesn't exclude some shortages in some specific areas such as risk assessment, operating experience and human factors. In addition the new Law 33/2007 requires CSN to increase cooperation with licensees regarding medical giagnosis procedures. This mandate in a field towards increase use will require additional resources.

The organization experiences very little turnover. Technical positions are required to be civil servants. Civil servants are required to have a college degree and pass a three phase exam that includes technical knowledge, language and communications and practical applications in conducting activities such as inspections. The vast majority of the CSN staff have many years of experience with the Regulatory body.

It is difficult to recruit technical staff at above the base-level. This may become a more important issue for the CSN to face as it seeks to replace the cohort of senior staff entering retirement. Further, staff with relevant professional qualifications outside nuclear engineering and radiological science may not be able to be employed as civil servants in the CSN. One example is staff with qualifications in psychology, important for dealing with issues of human factors and safety culture. The team recognises that change in this area must be consistent with developments in the Spanish public sector employment as a whole, but nonetheless believes that it deserves continuing attention.

Training

An internal training programme exists including mandatory courses for inspectors and the emergency preparedness staff. All technical staff of the CSN receives training in reactor technology and/or radiation protection. Specialized courses and assignments to other Regulatory Bodies are also offered to the staff. Operators have a high regard for the technical knowledge of the CSN staff.

Until now there has been no systematic approach to internal training at CSN based on organisational needs. However, a decision has recently been taken to implement the systematic approach to staffing and training according to the IAEA TECDOC 1254. A project manager has been appointed and a consultant engaged to design the system. Competence profiles will be developed for all organisational areas and gap analyses will be performed. On that basis the internal training programmes will be more stringent and tailored to the organisational needs. The system will also provide management with a much better tool for assessing the organisational competence and follow up of individual staff competence.

Although inspectors are provided an abundance of technical training there is limited training provided in soft skills such as report writing, communications and conflict resolutions. Soft skills training is provided

in other countries that have a similar risk informed oversight programme such as SISC (Risk Informed Inspection Programme Integrated in Plant Oversight process).

Complementary to the soft skills training other countries with similar oversight programmes have provided to the inspectors guidance in report writing to provide a clear description of the activities being conducted. This guidance typically is in the form of inspection reports templates that facilitate communication with the operators and the public.

CSN has a mature information management system with supporting data bases. Throughout the mission CSN personnel were able to immediately answer questions on regulatory activities. As the experienced CSN personnel retire there will be a need to transfer their knowledge to less experienced staff. Similar to other regulators CSN will be faced with the need to formalize their knowledge management system.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §4.6 states that "The *regulatory body shall employ a* sufficient *number of personnel with the necessary* qualifications, *experience and expertise to undertake its functions and responsibilities. It is likely that there will be positions of a specialist nature and positions needing more general skills and expertise. The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory* decisions."

S3 **Suggestion**: CSN should consider an approach that will facilitate the recruitment of staff at above the base-level for technical staff and non technical professionals.

(1) **BASIS**: GS-R-1 §4.1 states that "The *regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and* fulfilling *its functions* effectively *and* efficiently. *The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities. The structure and size of the regulatory body are influenced by many factors, and it is not appropriate to require a single organizational model. The regulatory* body's *reporting line in the governmental* infrastructure *shall ensure* effective *independence* from *organizations or bodies charged with the promotion of nuclear or radiation related technologies, or those responsible for facilities or* activities."

S4 **Suggestion**: The plans to enhance the organizational expertise in risk assessment, operating experience and human organization factors should be implemented with high priority. Other resource skill allocations should consider new facilities being proposed as well as the new demands in security, communications, international relations and compliance with law 33/2007 regarding radiation protection of patients.

(1) **BASIS**: GS-R-1 §4.7 states that "In *order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and* maintained, *the regulatory body shall ensure that its* staff *members participate in well* defined *training programmes. This training should ensure that* staff *are* aware *of technological developments and new safety principles and* concepts."

S5 **Suggestion**: The training of CSN inspectors should consider the addition of soft skills training such as communications, report writing and conflict resolution.

3.3. Advisory bodies

Advisory bodies

CSN has the authority to establish Technical Advisory Bodies. They do not have a permanent technical advisory body as is customary by many Regulatory Organizations. A temporary technical advisory group was established after the Vandellos II event to advice CSN with respect to this event. A recent advisory committee was mandated by Law to provide advice to CSN regarding transparency of their activities. These recent mandated changes and increases in the size of the organization have raised questions with the structure of the organization specifically with respect of the high level structure. While the organizational structure is best defined by the regulatory organization based on the country Government structure and processes, it is customary by mature regulatory organizations to have a technical advisory group to enhance technical decision making. The technical advisory group is typically a part time group consistent of technical subject matter experts.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §4.9 states that "The *government or the regulatory body may choose to give formal structure to the processes by which expert opinion and advice are provided to the regulatory body; the need or otherwise for such formal advisory bodies is determined by many factors. When the establishment of advisory bodies is considered necessary, on a temporary or permanent basis, such bodies shall give independent advice. The advice given may be technical or non-technical* (in advising, *for example, on ethical issues in the use of radiation in medicine). Any advice* offered *shall not relieve the regulatory body of its responsibilities for making decisions and* recommendations."

S6 **Suggestion**: CSN should use its authority to establish a technical advisory committee.

3.4. Interfaces and liaison with licensee's and other organizations

Relations with Operators

CSN aims at an open and frank relationship with the operators. In addition to professional Regulatory contact (e.g. inspections, licensing issues) CSN meets the operators periodically. Although there appears to be open and frank relationship with the operators there is no written instruction that delineates this objective.

Operators expressed concern at the implementation practices recently implemented to comply with the new law on transparency. Although they were fully supportive of transparency they have reservations with the immediate manner that information was made publicly without adequate time to verifying its accuracy.

3.5. International co-operation

CSN has relations on a regular basis with the International Atomic Energy Agency (IAEA), participating at the meetings of the different Conventions, and dealing with a very large spectrum of activities including membership in various committees (CSS, NUSCC, RASCC, WASCC and TRANSCC).

CSN is an active player in the different associations of Nuclear Regulators (INRA, WENRA and the Iberoamerican Foro).

CSN has also developed extended bilateral agreements with neighbouring countries as well as China, Russia, Korea, UK, Sweden and USA. These bilateral agreements include exchange of information related to nuclear safety and radiation protection, join undertakings in the development of harmonized European Regulations, joint inspections and inspector assignment.

Although CSN is actively participating in International activities the benefit of this effort comes from a balanced approach. The need to keep abreast of technical developments, International standards update and regulatory practices requires that CSN prioritizes its effort to achieve a balance of this effort with other demands of the technical experts.

4. Activities of the regulatory body

4.1. Authorization

4.1.1. Nuclear Facilities

Nuclear facilities have been authorised in Spain since the 1960s. The related national legal framework has continuously been advanced. Today the regulatory process for authorisation has a strong legal base and is well organised by the CSN. The legal base includes sufficient means that past authorisations can be brought in accordance with current legal requirements.

Law specifies the type of authorizations needed for each type of facility and activities. Applications for authorization must be submitted to the Ministry of Industry and Energy. The Law on Nuclear Energy establishes sanctions for any activity carried out without license. For all nuclear safety and radiation protection matters CSN is the only legitimate authority to issue binding reports for authorisation.

The main actors involved in the licensing process are as follows:

- Ministry of Industry, Tourism and Trade (MITYC), to which the CSN issues the mandatory reports required for the granting of licenses for nuclear installations and regulatory proposals in relation to Nuclear Safety.
- Ministry of the Environment, due to the requirement for a nuclear installation environmental radiological impact statement to be drawn up.
- Ministry of the Interior, with which there is collaboration in the drawing up of provincial Emergency Plans for nuclear accidents and in their implementation.
- Ministry of Health and Consumption in relation to those aspects of protection of health which might arise as a result of exposure to ionizing radiations, and as regards regulatory proposals on Radiation protection.
- Ministry of Foreign Affairs, in relation to studies and collaboration in the signing of International Treaties by the Spanish Government, and in general to relations with international organizations.

In general, a similar process applies to authorisations of nuclear power plants, fuel cycle and waste facilities, modifications of such facilities, decommissioning, discharge control and environmental surveillance, as to other nuclear and radiation facilities, as laid out in the Royal Decree 1836/1999[1], article 12 for nuclear facilities and article 38 for radiation facilities. For a nuclear facility, article 12 of Royal Decree 1836/1999 requests the following authorisations:

[1] Royal Decree 1838/1999, of 3 December, aproving the Regulation on Nuclear and Radioactive Facilities, modified by Royal Decree 35/2008, of 18 January..

- Prior site authorisation.
- Construction authorisation.
- Exploitation authorisation.
- Modification authorisation.
- Authorisation for the execution and assembly of the modification.
- Dismantling authorisation.

For nuclear facilities discussions with counterparts cover among others:

- Types of licenses as preliminary, construction, operation, modification, decommissioning and related limits and conditions.
- Format and content of authorisations issued by the MITYC and related reports of the CSN - Safety reports and their regular updating.
- Safety related documents as Operating Regulations, Plant Technical Specifications; On-Site Emergency Plan, Quality Assurance Manual, Radiation Protection Manual, Radioactive Waste Management Plan.
- Assessment and inspections of SSCs in the context of the authorisation process.
- Use of deterministic and probabilistic safety in assessments during authorisation - Accident analysis and verifications.

Each application has to be supported by safety analyses and related documentation.

Authorization of all nuclear facilities is processed by CSN under a well established process, with some differences according to the specifics and complexity of the installations.

Each nuclear installation has a Project Manager (PM) at the CSN; one of his/her main functions is precisely to ensure performance of the established processes needed for review of compliance with all relevant regulations and guides. The PM monitors the compliance with deadlines and assesses, or asks to assess, the appropriate fulfilment of the conditions.

The applications for authorization are reviewed and assessed by the CSN in accordance with clearly defined written procedures. The reviews, inspections and assessments are done based on the compliance with the regulations of the country of installation design origin as applicable. The content of the application is different according to the activity. There is a Management Procedure where the criteria and systematic for the assessment of the applications from Licensees are established.

The CSN has issued guidance to the operator on the format and content of documents to be submitted in support of an application for authorization. There are guides with the detailed content of documents as: Radiation Protection Manual, On-site Emergency Plan, Organisation Manual and Quality Assurance Manual. For the other required official documents, there are standard contents as practiced in the country of

origin of the design. According to the CSN policy, it was considered as not necessary to develop respective standards.

The deadlines for sending additional information when the documentation is incomplete are established in the RINR. The deadlines for the applications for renewal of an operational license and other documentation of the authorization are established in the authorization of each plant. A minimum period of 6 months is established in internal CSN process descriptions for the official submission of an application for authorization. For complex authorization cases the preliminary assessment may start prior to the official receipt of the documentation. When, in order to issue its perceptive report, the CSN has to request additional information from the licensee, it grants the latter a period of 15 days, extendable, for the answer. As a general rule, the licensee usually asks for this period to be extended.

The overall results of the review process is documented by the Project Manager in the "Proposal for technical decision (PDT)" to be endorsed b the CSN plenary and then submitted to the Ministry. The content of the license is specified adequately in the Law.

In an annex to the authorization for operation binding conditions and limitations are issued to the licensee regulating the operation as well future interactions with the regulator. It fixes the documentation on which the license is based, the treatment of modifications to such documentation or to the design and operational modes as well the annual reports. These reports have to encompass design modifications; internal and external operating experience; applicability to the facility of the new requirements issued by the regulatory body of the country of design origin, programme for training staff whose jobs may impact safety; results from the environmental radiation monitoring programme; staff dosimetry results; radioactive waste management plan activities; and operating life management activities.

The CSN report for granting or refusing an authorization is published on the CSN's external Website. The criteria whereby the authorization is accepted or rejected are presented, and if accepted, the conditions under which the operation of the installation or facility is granted are specified.

The CSN has in place the procedures established for subsequent amendment, renewal, suspension or revocation of an authorization.

Modifications must comply with what is indicated in Articles 25, 26 and 27 of the RINR. The modifications of the official operation documents must comply with the law and related conditions of the operating licenses. The CSN may stop the work in the event of the appearance of anomalies that affect nuclear safety; it may propose the revocation of the authorization if the anomalies cannot be corrected. It also has the power to suspend the operation of the facilities or the activities being carried out for nuclear safety or radiation protection reasons. In this case, the review and assessment process is the same as for other applications. There is no specific process for the suspension or revocation of an authorization but there is a generic process that can be used in such cases.

There are requirements for the timely submission of applications for renewal or amendment of authorizations.

The operating license for nuclear power plants is granted for 10-year periods, as appears in the Operating License (OL) itself, which establishes that for its renewal a Periodical Safety Review (PSR) must be submitted in the terms laid down by the CSN by means of a Complementary Technical Instruction. The renewal application must be submitted 1 year before the expiration of the validity period. The RINR determines when the CSN has to submit its Report to the MITYC (1 month before the deadline). Safety Guides establish the detailed content and scope of these reviews. Internal CSN procedures specify the review and assessment as well the time allowed for the necessary assessment.

4.1.2. Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services

General

Radiation facilities and X-ray devices for medical diagnostic purposes

Radiation facilities[2] are subject to licensing, while X-ray devices for medical diagnostic purposes are subject only to registration. In a larger hospital, the licenses are normally given to the department of nuclear medicine and to the radiotherapy department separately. In addition there are certain requirements for the staff: In radiation facilities the supervisor and operators must be authorized by the CSN. In facilities with radiation therapy and nuclear medicine, there also must be a radiation protection service authorized by the CSN. In X-ray facilities for medical diagnostic

purposes, the qualification of the staff, including the director and the operators, are addressed in the regulations. It was reported that there are currently 1334 authorized radiation facilities: Medical (358), industrial (738), commercial (62), research and training (176). Additionally there are 27030 registered medical x-ray facilities. These include conventional and specialized x-ray practices (4830), dental x-ray (19800) and veterinary x-ray (2400).

Radiation protection services

There are currently 126 approved services for radiation protection (RP) services in Spain, 62 of them in hospitals. Radiation facilities that provide both radiation therapy and nuclear medicine, as well as X-ray, are obliged to have an internal RP service. They may as well also serve small hospital in the area around. In addition there are independent RP services. The RP services are directly authorized by the CSN, their main responsibility are staff and public protection, but they also provide guidance on quality control of equipment and patient dosimetry in collaboration with other health authorities.

Dosimetry Services

There are currently 22 approved services for external dosimetry and 9 approved services for internal dosimetry serving about 85000 (65000 in hospitals) exposed workers annually. CSN safety guide 7.1 for dosimetry services does not require quality accreditation (ISO) as a prior condition for authorization in Spain. On the other hand, all applications are managed by CSN centrally by means of an extensive application form and technical assessment. The requirements are the same whether the dosimetry service is small or large. The authorized dosimetry laboratory sends the dosimetry results to the CSN for registration

[2] In the Spanish legislation, medical practices are grouped into either radiation facilities or X ray devices for medical diagnostic purposes. A "facility" is one or more pieces of equipment owned by one legal person.

in a national dose register on *a monthly basis.* This is the basis for personal dose statistics for various categories of workers in Spain. The monthly report also goes to the licensee (supervisor) and to the radiation protection center, if present in the facility. The licensee is responsible for implementation of the optimisation principle, and for investigating possible high doses to individuals. This system of surveillance gives a nice overview of the occupational doses in Spain and also an indication of which individuals may approach the dose limits. 99.7% of all exposed workers in Spain receive occupational doses less than 6 mSv. The personal dose data in the CSN register is committed to the highest level of confidentiality. CSN is issuing a general report annually (trend analysis) based on the specific reports from each of the dosimetry laboratories.

Radiation Facilities are subject to a licensing process established in the Regulation governing Nuclear and Radiation Facilities. Likewise, the practices that only require registration and the practices that are exempt are included in the aforementioned Regulations and in the Regulation on Health Protection against Ionizing Radiations[3].

The IRRS team was informed that X-ray devices for medical purposes like computer tomography or angiography are only subjected to registration. It is not expected from the CSN point of view that, even if there is a real potential for radiation injuries to workers to occur in such facilities, a higher level of scrutiny (namely licensing) would significantly improve the effectiveness of the radiation protection; focus on inspections and training the operators, in such practices is considered to be a more efficient tool.

The CSN ensures that, prior authorization, notification or an exemption system is in place for *Radiation Protection Services* and *Personal Dosimetry Services.* This is established in the Law creating the CSN Law (Article 2.h) and the Royal Decree 783/2001 (Article 24 and 27.2)

Requirements for license

Radiation facilities

Article 38 of the Regulation governing Nuclear and Radiation Facilities[1] establishes the documentation that applicants must attach to licensing applications, among which a safety study is included. This documentation is assessed by the CSN before it issues its report on the licensing. The principles of justification of the practice are considered during the licensing process. An advanced database / management information system is used by the CSN to record all information in relation to the licensing process.

The applications for obtaining the respective licenses are reviewed and assessed by the CSN in application of the current Legislation (Article 2.b) of the Law creating the CSN and complying with the existing technical procedures that apply to them.

In addition, the Law on Nuclear Energy[4] and the Regulation governing Nuclear and Radiation Facilities[1] establish that a commissioning inspection has to be conducted in order to check that the construction and assembly of the facility follow the design submitted to apply for its license and that all the safety and

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[3] Royal Decree 783/2001 of 6th July, approving the Regulation on Health Protection against Ionising Radiations (BOE 178, of 26th July 2001).
[4] Law 25/1964, of 29th April on Nuclear Energy.

protection requirements defined in the documents submitted with the licensing application and the limits and conditions set in the corresponding licenses and the current legislation are met. This also allows for observations on the radiation safety culture to be made before a license is issued.

The requirements for granting a license to radiation facilities depend on the type of facility and its associated hazards. In the Regulation governing Nuclear and Radiation Facilities, radiation facilities are classified in a 1st, 2nd and 3rd categories. Furthermore, by means of an internal Procedure (PG-IV-02) the CSN classifies the licensing applications from radiation facilities in 4 groups, according to the hazard associated with each one of them, to which different stages and scopes of the assessment and review processes apply.

The new version of the RINR (Article 40) provides for different processes to process the design modifications of radiation facilities, taking into account their significance from the radiation safety point of view. The internal technical procedure PT IV 58 provides a good and harmonized basis for the review of the documentation submitted, the format for the report to be issued by the CSN and the model conditions for the facility.

Radiation Protection and Personal Dosimetry Services

Applications for authorization are reviewed and assessed by the Regulatory Body in accordance with Procedures PG.VII-01 and PT.IV.33.

The processes and requirements are commensurate with the potential magnitude and nature of the hazard presented. The degree of exigency in the assessment preceding the license is commensurate with the significance of the activities to be carried out by the applicant (see e.g. Article 3.1.3 of CSN Instruction IS-03).

Documents to submit for a license applications

Radiation facilities

The Regulation governing Nuclear and Radiation Facilities establish the basic content of the documents that licensees must send in support of their licensing applications. The content of these documents is commensurate with the hazard associated with the facility in question. There are CSN Safety Guides where the content of the documents to be submitted as well as that of the Radiation Protection Manual are established in detail.

According to Article 4 of the Regulation governing Nuclear and Radiation Facilities, when the applications to obtain any licenses are submitted, the Industry Executive Organ (Ministry or Autonomous Community) checks if the former are incomplete or inadequate. If so, the licensee will be required to complete or expand the documentation within 10 days (Law 30/92, of the Legal Status of Public Administrations and the Common Administrative Procedure). In general it takes approximately five months[5] to issue a license but may take longer for more complicated applications.

When, in order to issue its report, the CSN has to request additional information from the licensee – in accordance with Article 6 of the Regulation governing Nuclear and Radiation Facilities – a 2-month period is granted for the latter to answer. This period of time is set in the document for requesting said additional information.

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[5] From the initial application to the license issuance.

The stages of the licensing of radiation facilities are included in Title III of the Regulation governing Nuclear and Radiation Facilities as well as in the different licenses required for said Facilities: Operating Licensing and Commissioning Notification, according to Articles 38 and 39 of the RINR. Furthermore, the licenses for Changes and Modifications (Article 40) and Dismantling and Decommissioning (Article 41 and 42) are provided for. This also applies to licensee change.

The conditions for issuing the licensing in each of these stages are established taking into account the results of the assessments and inspections conducted in each case. A specific licensing must be obtained for each of the stages.

The licensing process itself forces to consider the results of previous stages in each licensing stage. The follow up and assessment corresponding to the application in question are carried out in each of the licensing processes, and, if appropriate, an inspection visit is also conducted. A full check of the operation of the facility as a whole is performed in each Modification licensing. Licenses are issued for an indefinite duration, unless radiation facilities are modified or their license revoked.

Radiation Protection and Personal Dosimetry Services

The Regulatory Body issues guidance on the format and content of documents to be submitted in support of an application for authorization. The content of the information is established in CSN Guides 7.1 and 7.3. The applicant is required to submit or make available to the regulatory body, in accordance with agreed time-scales, all information that is specified or requested.

License conditions and limits

Radiation facilities

In granting these licenses, the CSN sets a series of performance technical specifications to be fulfilled by the licensee. These specifications include periodic reports and information about certain operating conditions that the licensee has to send to the CSN periodically or at a given time; for example, during the first year of operation, the monthly readings of an area dosimeter in certain areas adjoining the bunker of a linear accelerator will be sent to the CSN, etc.

In order to grant the licenses, the CSN prepares an assessment report in which the criteria whereby the licensing application is accepted or rejected are established. From the aforementioned report, the CSN issues to the Industry Executive Organ (Ministry or Autonomous Community) a Technical Report defining the conditions (technical specifications) that will govern the operation of the facility when the licensing is accepted.

On the other hand, the CSN may halt the work in the event of the appearance of anomalies that affect safety; it may propose the revocation of the licensing if the anomalies cannot be corrected. The CSN may also suspend the operation of the Facilities or the activities carried out for safety and radiation protection reasons (6).

Radiation Protection and Personal Dosimetry Services

Procedure PG.VII.01 (personal dosimetry services) establishes that the technical opinion proposal will be accompanied by a report that supports the decision to be made (granting or refusing the license). Procedure

PT.IV.33 (radiation protection services) follows the same approach for the granting of the license. The process to refuse a license is addressed in the general regulations; however it is not yet described in the internal procedures, because this option is very rare.

Modification, renewal, suspension, revocation of a license

Radiation facilities

The issuance of reports related to licensing, modifications and renewals as well as reports related to executive requirements such as the suspension, intervention and revocation of licensing is included in the Law creating the CSN, the Regulation governing Nuclear and Radiation Facilities and Management Procedures PG.IV.02 and 06. Moreover, the CSN may suspend the operation of the Facilities or the activity carried out for safety and radiation protection reasons according to management procedure PG.IV.06.

Licensing changes and modifications are regulated by an administrative procedure similar to that of applications for new license. The new version of the RINR (Article 40) provides for different processes to process the design modifications of radiation facilities, taking into account their significance from the radiation safety point of view.

As in any procedure, all reviews and assessments are commensurate with the hazard associated with the facility in question, in accordance with the classification of the Facilities in 1st, 2nd and 3rd categories defined by the Regulation governing Nuclear and Radiation Facilities and with the classification that the CSN makes, according to internal Procedure PG-IV-02, in 4 hazard groups.

Radiation Protection and Personal Dosimetry Services

Procedures are established for any subsequent amendment, renewal, suspension or revocation of an authorization. The requirements for a timely submission of applications for renewal or amendment of licenses are also documented:

The actions to be taken in the case of a modification of the technical and human means that were the basis for granting the license are defined in the conditions included in the licenses.

The processes to be followed in the case of revocation of a license are established in Procedures PG.VII.01 and PT.IV.3.

The licensing process being implemented by the CSN for medical and industrial practices is satisfactory and reflects the main safety requirements given in GS-R-1. The day to day activities of the CSN in discharging its functional responsibilities in this area are well established.

The database / management information system developed by the CSN for licensing purposes, registration purposes, inspection reports, equipment and source inventory etc., that holds all relevant records in digital format could be an example of a well researched, well resourced and well managed system that is used by the CSN and its associated regional authorities.

Ideally applicants should be aware of the typical conditions of the licensing in advance of the licensing being issued. The team noted that a CSN Instruction is being developed in this area.

The system of radiation protection services in Spain seems well functioning, and may be an important resource when going into deeper collaboration about patient protection with other health authorities as emphasized in the New Law 33/2007 7th November (Article I. h).

The CSN management of the dosimetry laboratories seems very thorough, and from what was observed by the IRSS team, there seems no doubt that the occupational workers in Spain get a monthly assessment of their dosimeter reading of high accuracy.

4.1.3. Decommissioning, Waste and Remediation and Environmental Surveillance

General

In general, a similar process applies to authorisations of waste facilities (including facilities for spent fuel management), modifications of such facilities, decommissioning, discharge control and environmental surveillance, as to other nuclear and radiation facilities, as laid out in the Royal Decree 1836/1999[1], article 12 for nuclear facilities (as specified in Chapter 4, section 1.1 of this Report) and article 38 for radiation facilities.

The IRRS review team has studied how aspects of the authorisation system are applied to authorisation of a disposal facility, to discharges and environmental surveillance, and to decommissioning. These cases will be reviewed below.

Two further cases, the construction of an on-site dry storage facility for spent fuel at the Trillo and José Cabrera NPPs, have been considered; as the authorisations are treated as *plant* modifications, *they* follow the general procedures for authorisation of modifications and will not to be specifically reviewed here. In relation to this, the IRRS team also studied aspects of the approval of the spent fuel dry storage casks, which have been approved following the binding report of the CSN (according to Article 80 of Royal Decree 1836/1999), but these aspects will not be considered further in this report.

Authorisation conditions for the El Cabril facility

The El Cabril (Sierra Albarrana, Province of Cordoba) disposal facility for low and intermediate level waste (and its auxiliary facilities) is the unique recipient for low and intermediate level waste in Spain, and a cornerstone in the national infrastructure for radwaste management. By definition, the facility is considered a nuclear facility, although it receives waste from both nuclear and radiation facilities. The licensee is ENRESA (Empresa Nacional de Residuos Radioactivos, S.A.). The current authorisation entered into force on the 8 October 2001[6], was issued by the Ministerio de Economía, and is valid until the volume of the facility has been occupied, and provided operational experience so permit. The authorisation contains provisions, *inter alia,* as follows:

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[6] Ministerial Order for operating authorisation of nuclear installation for solid radioactive waste disposal in Sierra Albarrana.

- The operator should take into account the volume and activity limits referred to in the authorisation, bearing in mind that they may change following initiatives taken by the operator, or upon request by the CSN.
- The authorisation may be revoked at any moment following non-compliance or discovery of unfavourable factors unknown at the time of licensing.
- The operator should take necessary steps to assure adequate protection (security provisions); and,
- The operator should provide an updated safety assessment report elaborated in accordance to the instructions issued by the CSN, at minimum every 10 years.

Modification of design is considered in the authorisation, establishing the requirement to request an authorisation for the modification from MITYC if criteria, norms and conditions need to be altered.

Through the authorisation, the operator has the right to:

- Receive, treat and condition low and intermediate level waste.
- Store in cells on the storage platforms such waste that conform to the acceptance criteria for disposal.
- Use correlation factors for establishing the inventory of certain nuclides that are difficult to measure, in a manner that is acceptable to CSN.
- Perform sampling and studies as necessary to characterise the waste.
- Store waste on site that do not comply with the acceptance criteria for disposal.

The life-span of the facility is divided into three phases: the operational phase, the control phase during which no more emplacement take place (foreseen to last for 300 y), and the release phase in which no restrictions due to radiological considerations in the use of the site are foreseen. The inventory should be limited to, at the end of the operational phase, comply with a limit of 2E+04 TBq for Co-60 (dominating nuclide), and with limits of the inventory for a number of other nuclides, e.g. Ni-63, Sr-90 and Cs-137, that are approximately one order of magnitude lower. The inventory limits for total alpha emitters are also specified.

Other provisions apply as well, e.g. on design modifications, annual reporting, and surveillance. Furthermore, the authorisation grants the right to CSN to develop complementary instructions that build on and elaborate the provisions in the authorisation. CSN has issued such complementary instructions[7], which consider quality assurance, the manual for radiation protection and safety assessment, modifications, changes in the normative system, competence of staff, surveillance, dosimetry, and control and inspection.

The Centre de l'Aube facility in France serves as reference facility for El Cabril. This means that to some extent, French guidelines have been incorporated and, as appropriate, adapted to the particular conditions prevailing in Spain. The aforementioned instruction issued by the CSN on the basis of the ministerial authorisation makes specific reference to the Centre de l'Aube facility, with regard to the obligation of the operator to take into account new recommendations and requisites concerning safety and radiation protection developed in international fora or in countries operating similar facilities, *in particular* such that apply to the Centre de l'Aube facility. It is also specified that operational experience from similar facilities,

[7] Complementary Technical Instruction on limits and requirement for operating authorization.

in particular the Centre de l'Aube, should be considered in maintaining and improving the characteristics of the El Cabril facility.

Discharges and environmental surveillance

The authorisation of discharges to the environment follows the general procedures described above. Thus a preliminary authorisation based, largely, on site characteristics, has subsequently to be developed into the authorisations for actually executing the operations.

Technical guidance for installation of systems for discharge authorisations for NPPs stem largely from the country of origin of the facilities, e.g. NRC standards on discharge limitation as laid out in the Code of Federal Regulations apply. Discharges should also be limited to comply with a 'limit' of 0,1 mSv per year to the most exposed individual of the critical group, assuming conservative basic characteristics of the group. The value of 0.1 mSv comes from a study by CSN including comparison to standards in other European countries and taking into account the original limits of the US Code of Federal Regulations that lead CSN to conclude that it was appropriate to include this value as a general constraint in the technical specifications for all NPPs. Site-specific rules define how the 0.1 mSv can be proportioned between liquid and gaseous discharges.

The technical specifications governing the operation of the plant also implement the provisions of the CSN Safety Guides 1.4 on discharges and discharge monitoring[8], 4.1[9] on environmental monitoring programmes and 7.9 with regard to off-site dose calculation[10], that gives guidance also on the effluent control and environmental monitoring programmes. It is with the CSN responsibilities to authorise discharges to the sewer system from radiation facilities, based on total activity as well as on activity concentration. Assumptions underpinning dose estimates for such discharges authorisations have been verified in different projects, e.g. in Valencia. Hold-up tanks for delaying discharges of waste containing radioactive iodine are used in hospitals.

Decommissioning

The procedural basis for the decommissioning and dismantling of nuclear facilities is laid out in the Royal Decree 1836/1999, Title 2, Chapter 6. Article 29 specifies the requirement for a dismantling authorisation and a declaration of closure, where dismantling is understood as "all those activities carried out once the corresponding authorisation has been granted which allow for the presentation of a request for a declaration of closure and which shall imply the total, or restricted liberation of the site".

Development of the mandatory documents as specified in RD 1836/1999 occurs parallel to the transfer of responsibility from the operator to ENRESA. On the basis of the CSN Safety Report, the MITYC grant the dismantling authorisation, together with an authorisation of transfer of responsibility for operation of the facility to ENRESA. Actual dismantling operations are carried out by ENRESA. Following the finalisation of the dismantling activities in compliance with the plans underlying the authorization, and following a favourable review by CSN, the MITYC may finally issue a Declaration of Closure.

The radiological criteria for release of nuclear sites are defined in Instruction IS-13 from the CSN[11].

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[8] GS-1.04. Radiological control and monitoring of liquid an gaseous radioactive effluents released by nuclear power plants. CSN, 1988.

[9] GS-4.01. Desing and development of the Environmental Radiation Monitoring Programme for Nuclear Power Plants. CSN, 1993.

[10] GS-7.09. Manual for dose calculation outside nuclear power plants. CSN, 2006.

[11] Instruction IS-13, of 21th March 2007, of the Nuclear Safety Council on radiological criteria for the release of Nuclear Facility Sites (BOE of 7th May 2007).

A simplified process, in which the title-holder is responsible for the dismantling operations, but similarly leading to a Declaration of Closure issued by the MITYC upon a favourable report by the CSN, applies to the decommissioning of radiation facilities (Royal Decree 1836/1999, Article 41).

In the areas of radwaste authorisations, relevant to spent fuel management, discharge monitoring, environmental surveillance and decommissioning, covered by this review, an appropriate structure is in place. It is observed that many of the actual provisions for the operation of the facilities are embedded in the authorisations, whereas relatively few of the requirements have been specified beforehand as generally applicable requirements. Authorisations cover all relevant aspects of the operation of the facility in question, also providing a high level of protection of the public, e.g. in the case of discharge authorisations, which is verified through an extensive environmental monitoring programme.

4.2. Review and assessment

4.2.1. Nuclear facilities

Review and assessment of safety submissions from Spain's NPPs is performed at CSN's headquarters in Madrid, in the Divisions of Nuclear Engineering and Nuclear Technology. These Divisions have sufficient technically expert staff resources to enable routine assessments to be performed in-house by CSN's own technical experts. In addition, management arrangements are in place to enable CSN to use external technical support organisations in times of peak demand and when advice is needed in particular specialist areas.

Review and assessment tasks are initiated by requests from NPP operators for authorisations in accordance with Royal Decree 1836/1999, which approves the regulation of nuclear and radioactive installations, in response to mandatory reports of plant events, and as a result of internal CSN initiatives and requirements for the submission of other safety documentation. The authorisations include permits for commencing each new stage of plant life such as prior authorisation, construction, operation, Decennial Permit Renewal and decommissioning. The regulatory system has a graded approach to permissioning, so that safety significant changes at NPPs require authorisation before implementation, whereas changes with minor or no safety significance may be implemented by the NPP operator and reported to the CSN subsequently. The criteria for seeking prior authorisation for modifications are clearly specified in conditions attached to NPP permits.

Discussions with counterparts included inter alia:

- Types and generic schedules for the different review and assessment processes.
- Internal guidance for the performance of CSN reviews and assessments.
- Guidance for the review of periodic safety reviews.
- Complementary instructions regarding the licensing base for operating plant.
- Complementary instructions regarding standards for conditional applications for licensing renewal.
- Practices and results from discussions with licensees on their submittals for review and assessment.

- Final results of reviews and assessments (Proposed technical reports to be submitted to the plenary).
- Reporting and assessment of operational experience and events, related event databanks and follow up actions.
- Ageing management programme.
- Review and assessment of human and organisational factors.
- Foreign operating experience and generic safety issues (TEMGE databank).
- Integrated PSA Programme and viability of models and results for review and assessment activities.
- Criteria for the application of PSAs.
- Requirements for the updating of PSAs.
- Use of PSA for the review of accident management; analyses related to primary-feed and bleed and containment venting and analysis of costs and benefits.
- CSN Programme for research and development 2008 – 2011 together with examples for completed projects and planned projects.
- Planning and training related to review and assessment.

The Royal Decree 1836/1999 establishes the requirement for NPPs to comply with Spanish nuclear safety requirements, and those of international institutions and the country of origin of the NPP design as applicable. The NPPs are responsible for identifying and reporting on those country of origin requirements applicable to their own plant and for considering the applicability of changes to them. The CSN reviews these reports to determine applicability and proposes changes to scope if it considers this necessary.

The country of origin requirements have been increasingly supplemented by CSN review and assessment of licensees' analyses of the impact of changes to them, and CSN has drafted Complementary Technical Instructions to rebaseline its regulatory position on these for the future. These new Complementary Technical Instructions identify for each of the NPPs the specific parts of country of origin requirements (for US designs, parts of 10CFR50 and 10CFR100) that apply now to set a baseline for changes in the future. CSN is aware that new Instructions may modify existing Instructions, resulting in a set of Instructions that is not user-friendly, so reviews the entire sets every five years and individual Instructions on a shorter timescale if necessary.

Assessment of Emergent Technical Issues

The response of CSN to a specific emergent issue at Cofrentes provided evidence on the depth of its review and assessment of the operator's technical submission and its own understanding of the plant design, safety concepts and operating principles. This issue arose from the discovery of liquid seepage from pipework associated with the control rod drive mechanisms during pressure tests at the end of a refueling outage, delaying return to service. CSN challenged the licensee's initial position that no plant modifications were required prior to return to service. The CSN determination report and technical assessment reports and notes were seen to demonstrate that CSN staff had performed a thorough technical assessment of the licensee's submission. CSN had also employed a contractor to provide detailed technical support to its own staff. A close relationship between CSN and the contractor had facilitated a rapid response, and the level of trust between the two allowed the work to proceed in parallel with the development of the contract for

supply of this service. Resolution of the issue by implementation of plant modifications was achieved in < 2 months. CSN's assessments in general are also facilitated by the direct access that CSN has to licensee information, including the computational codes and models it uses. This example showed the high technical capability of CSN's technical experts, its ability to engage prompt Technical Support Organisation support in relevant areas and its readiness to challenge licensees' positions.

Use of PSA

CSN started an integrated programme for plant-specific PSAs in 1986, to provide insights into safety of the plant and to provide baselines for future applications of PSA by the licensees, for example justifying exemptions to Tech. Specs. and managing varying risk levels during plant outages. Their scope was developed in cooperation with the licensees and other stakeholders, and expanded with time in the light of experience. As expected, the first PSAs revealed vulnerabilities and CSN required changes at the NPPs as a result. CSN started to require Level 2 PSAs from licensees in the 1990s including fire, flooding and seismic events, and these have now been completed for all Spanish NPPs. Further plant changes, for example, uprating of containment fans and installation of hydrogen recombiners, have been implemented as a result. CSN assessment of the PSA submissions has been facilitated by direct access to and use of the computational codes and models that the licensee uses. It has also performed a completely independent Level 2 PSA for Trillo using alternative models to check the sensitivities and obtained broadly similar results.

CSN recognises both PSAs and deterministic analyses, and the different insights that each provide. Licensees are conservative in their use of PSA and around 90% of safety submissions are based upon deterministic analyses. CSN seeks an appropriate balance between the two approaches, and has developed a Guide (1.14) on PSA applications such as Risk Informed Regulation. The latter is an option for licensees, but not mandatory, and both probabilistic and deterministic criteria must be satisfied.

CSN has developed and implemented a user-friendly PSA tool for use by staff not expert in the understanding of PSAs. This contains detailed plant data for each of Spain's NPPs and supports the SISC system and its Significance Determination Process. It includes simplified system diagrams, human reliability models and component models.

Level 2 PSAs have been used systematically to review and assess accident management procedures to ensure adequate coverage of vulnerabilities and dominant accident sequences. Plant specific licensee proposals on the need for particular measures such as primary feed and bleed or venting for a large dry containment have been assessed and discussed with the licensee to ensure optimal use of technical means and resources to reduce and control severe accident risk.

Assessment of Human Factors

CSN created a PSA assessment unit including human factors within its organisation in the early 1990s. At this time none of the Spanish NPPs directly employed human factors experts, relying upon contractors instead. CSN recognised that this was resulting in the utilities becoming dependent upon themselves and others for expertise in this area, so in 1999 it requested that they develop and implement programmes for improving their capability to analyse human factors and organisational change. As a result, all of the utilities recruited human factors specialists and CSN has worked with them to develop requirements on the

utilities for human factors analysis. Seven categories of change requiring human factors analysis are used, based upon WANO recommendations:

1. Organisational efficiency: structure, resources, etc.
2. Safety culture.
3. Human performance, including design modifications.
4. Self-assessment and knowledge management.
5. Plant status and configuration control.
6. Job and task management.
7. Equipment condition and performance, which include safety culture and plant design changes.

The NPPs now have written procedures requiring consideration of whether proposed plant design modifications require associated human factors analyses. CSN undertakes biennial inspections of the process, focussing on specific examples. Major modifications always require human factors analysis, minor modifications may not, but CSN continues to press utilities to increase the scope of human factors analysis. CSN allocates assessment effort to the human factors aspects of safety submissions in the same way as for other specialist areas.

Assessment of Organisational Change

The NPP operating permits require each utility to produce a document describing top-tier organisational arrangements, which must be approved by the CSN. Any changes to these must also be approved by CSN prior to implementation. In addition, the utilities have much more detailed 'Organisational Manuals'. CSN has required utilities to develop organisational change procedures, to underpin and control changes to the organisational arrangements set out in these manuals.

For any proposed organisational changes, CSN now requires utilities to set out the rationale for the change, analyse its impact, identify the enablers (e.g. training, communications) and then review implementation after 6 months. Utilities must report on organisational changes annually. CSN uses IAEA and NEA guidance to inform its assessments and usually focuses upon changes from the organisational baseline. It may also include inspections of the organisational change procedures in its biennial inspections.

Regulatory Body's Understanding of NPPs and Operating Principles

There is close working level interaction between CSN's resident inspectors and technical experts, and issues may be raised by individuals within both groups with their line managers for inclusion within CSN's work programmes. Once agreed and registered as 'initiatives', these internally triggered issues are managed through to resolution in the same way as externally initiated issues. Information about developments on the NPP sites is formally communicated by resident inspectors to CSN HQ every morning, and then on to the technical experts via subsequent open meetings with staff. There is also frequent direct face to face interaction between the resident inspectors and technical experts at the NPPs when team inspections are performed, and the resident inspectors attend meetings at CSN HQ every ~ 3 months. This indicates

collaborative working between different parts of CSN and a shared understanding of NPPs, safety concepts and operating principles.

Discussions with an NPP Plant Manager supported this and showed that there are good relationships between Plant Managers and their CSN counterparts. The utility respects the expertise of CSN's technical experts, and recognises that it and CSN share a common aim of enhancing nuclear safety. Although some areas for improvement were identified, these were regarded by the utility as relatively minor and raised in order to support continuous improvement within CSN from an already high baseline. CSN's regulation of the nuclear industry was regarded by the utility as having improved its nuclear safety and operating performance by challenging its ways of thinking.

Assessment and Feedback of Operational Experience

Event Notification Requirements for licensees are set out in IS-10. CSN currently undertakes short-and medium-term assessments of the reports, and long-term assessment processes are being developed. The Instruction sets out the format for notification, reporting criteria and timescales. Prompt reporting must take place within 1 and 24 hours and more detailed reports including root cause analysis must be submitted to CSN within 30 days. CSN has developed internal procedures and a graded process for reviewing and responding to event reports. Operating experience with Spanish plants is collected systematically in a databank which includes regulatory actions taken. Follow up actions have to be included in the licensees "corrective action programme". The "Limits and conditions" assigned to the authorisation require operational experience at both the licensed plant and other Spanish plants together with lessons learned have to be addressed in the annual licensee reports.

Operating experience with foreign plants and generic safety issues resulting from international sources are compiled in another CSN database on "Generic Safety Issues". This TemGe (Temas Genericas) database is used to keep track of such issues as well as of related licensees' actions if applicable as in the case of actions taken after the Forsmark event. Issues may remain open even though licensees have already taken some actions in response, and closed issues may be reopened if new information indicates this would be appropriate. So far TemGe has not been used as a tool for the management of safety related knowledge and for co-operation with other countries and international organisations on generic issues.

Aging Management

Aging management requires the anticipation of plant degradation mechanisms and monitoring of plant vulnerable to these to ensure that the potential safety impact is properly managed. CSN started with a pilot project based upon the US requirements in 10CFR54, but the scope has since been increased to support possible life extension. It focuses upon passive components in both safety systems and non-safety systems which are nonetheless important to safety, for example pressure boundaries and non-return valves, as the Maintenance Rule already covers active components. Following the Vandellós II event, which was caused by unrevealed plant degradation, CSN worked with the UNESA utility association to learn the lessons and develop a guide in this area. It has placed new requirements to improve aging management programmes upon individual NPP operators via Complementary Technical Instructions, and it includes inspection of these in the SISC. CSN is also planning to issue a high level Technical Instruction (IS) on aging management later this year.

Research into novel issues

Law 33/2007 amending Law 15/1980 creating the CSN places a duty upon the CSN to set-up and monitor research plans within the field of nuclear safety. The purposes of research are to support CSN's regulatory activities, assist with its staff development and support the maintenance of Spain's nuclear infrastructure, for example university departments. The research issues are identified and proposed by CSN's Technical Directorates, and these also provide the rationale for the research projects aimed at their resolution. They include both short-term projects supporting regulatory decisions and longer-term projects aimed at broader and generic issues. CSN participates in international programmes where this is beneficial to resolution of the issues. The current four year programme for 2008-2011 has just been endorsed by the CSN Plenary. The programme is a chance to strengthen CSN's competence in key safety areas.

CSN and licensees develop a collaborative jointly funded research and development programme, which the CSN Plenary reviews and agrees each year. An annual public meeting is held with licensees to discuss the report of the results and propose future work. A wide range of research is undertaken including, for example, severe accident phenomenology. The report is circulated to CSN staff involved in drafting instructions and guides so that these may reflect the latest understanding.

CSN has a well-developed system for the management of review and assessment. This includes weekly management meetings at which progress with the work programme is monitored, new tasks are added, work priorities are reviewed and resources allocated.

During all the discussions with CSN staff, documents of all types were made readily available via the CSN intranet. Auditable trails were immediately available for viewing and the CSN IT-based document management system supports consistent regulatory decision-making by providing staff prompt access to previous regulatory decisions and the technical assessments underpinning them.

CSN intervention in licensee change proposals, which may include organisational change, is graded according to the potential safety significance of the proposals.

Safety significant changes at NPPs require authorisation before implementation, whereas changes with minor or no safety significance may be implemented by the NPP operator and reported to the CSN subsequently. The criteria for seeking prior authorisation are set out in conditions attached to NPP permits.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.9 states inter alia that 'the *regulatory body shall acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the* operator'

G2 **Good practice**: CSN has developed and implemented a user-friendly PSA tool for use by staff not expert in the understanding of PSAs. This contains detailed plant data for each of Spain's NPPs and supports the SISC system and its Significance Determination Process. This PSA tool enables all CSN technical staff, and not simply those who are experts in PSA, to understand the plant systems and operational conditions important to safety. In addition a special PSA tool is available on the CSN intranet for use by all inspectors The tool facilitates the risk-informed selection of the SSC for the SISC inspection.

4.2.2. Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services

In radiation facilities, the objective of the assessment is to verify, through licensing documentation, agreement of the facility design with the applicable regulations and the establishment of an adequate safety and protection level. For dosimetry service entities, the assessment will consist of verification of the quality accreditation. For laboratories without accreditation the assessment also covers the quality assurance (QA) aspects prior to authorization.

Except for the specific case of personal dosimetry services, the process of assessment and review of the technical documentation attached to the authorization applications are commensurate with the nature and potential magnitude of the associated hazards: classification of radiation facilities in 3 categories[1] (the Law establishing the CSN and the RINR); internal CSN process of classification of the applications in four groups according to potential hazards and the complexity of the facility (PG-IV-02). The allocation of resources and the proposed actions are related to the above classifications.

Additionally, Procedure PG.IV.06, states that the information about the regulated practices may be obtained by direct or indirect means. Direct information is mainly obtained by means of inspections and from the information provided by the activity or practice authorization holder itself, such as periodic and non-periodic reports, event and incident notifications and documentation provided for authorization processes after the initial operating authorization.

Secondly, the indirect information is basically obtained from reports sent by entities that market radioactive material and radiation-generating equipment, reports from entities that provide Radiation Protection Services to the Facilities and complaints or accusations made by individuals, associations, other bodies from Public Administrations and the Courts of Justice.

For dosimetry service entities CSN performs a review and assessment of information submitted by applicants as established in Procedures PG-VII-01 and PT-IV-33.

The review and assessment of processes of authorization and control of radiation facilities are based on what is established in the Regulation governing Nuclear and Radiation Facilities, Regulation on Health Protection against Ionizing Radiations, CSN technical instructions, CSN Safety Guides, technical procedures applicable to each type of facility, authorization documents of each facility and Technical Standards that apply (BSS, ICRP, NCRP, ISO, UNE, etc.). This is the way CSN defines and makes available to the operator the principle and associated criteria on which its judgements and decisions are based.

In addition, the team has been informed about meetings organized between CSN and applicants to discuss time schedule, review and assessment. Regular meetings with Spanish radiation protection societies and the Spanish health physic society are also organized to discuss review and assessment issues. Review and assessment also takes into account experience feedback from events. The team was presented as an example the circular letter CSN/C-DRR-14/03 No. 2/2003 about the Gammagraphy equipment TO-660 rupture between source holder and driving device containing detailed information on the event and the lesson learned. Considering the number of review and assessments performed by CSN in the area of radiation

facilities in comparison with nuclear facilities, the IRRS Team has underlined the great involvement of CSN in sharing its review and assessment criteria to licensees.

Furthermore, the applicable Regulations and the corresponding acceptance criteria are included in the assessment reports. Once the aforementioned assessment report has been written, a Binding Technical report proposal that includes the limits and conditions for the operation of the facility is prepared. Technical Report proposals are approved by the CSN's Plenary Meeting. Additionally, the checks carried out by the CSN during its inspection visits are included in Reports that are sent to the authorization holders so that they may express their consent or make declarations regarding the content of the Report. The results of the assessment of Inspection Reports are notified to licensees, if appropriate, by means of control documents and other channels provided for in Management Procedure PG.IV.06. The principles of justification of the practice are considered during the authorization process. Justification analysis of new applications in the use of ionization radiation has no formal guidance and is made on case by case basis.

Should the documentation provided by the owner not be sufficient, correct or accurate, the CSN indicates the missing or defective documents to the owner and requires it to be rectified.

After the facility license has been issued by CSN and before commissioning the facility, an inspection visit is carried out to verify that the license limits and operational conditions have been implemented and are effective.

CSN satisfies itself that in particular, novel technical solutions, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety. The team has been informed about such a testing being performed for a new shielding material used in a radiation therapy bunker. The testing showed hot lines and therefore CSN required consecutively additional reinforcement.

Annual work plan

General

The CSN's Annual Work Plan defines the generic annual programme of activities for assessment and review of radiation facilities and dosimetry services.

Radiation facilities

Regarding radiation facilities, it appears from the annual licensing workload presented to the team, that CSN has issued for a typical year a total of 357 assessment reports (56 for new radiation facilities, 246 reports dealing with modifications and 55 related to decommissioning); in the same time, 358 applications were sent to CSN (60 for new radiation facilities, 251 for modifications, and 47 for decommissioning). This figures show a good balance between the available resources and the current workload. However, the team was informed about new requirements (e.g. security issues) that reviewers will have to take into account in the future and that may have a significant impact on the workload.

Procedure PG-IV-0.2 establishes the processes for processing the applications related to them. Likewise, there are software tools to support the management of radiation facilities dossiers.

Within the CSN Radiation Protection Department, the Operational Radiation Protection sub-department centralizes the process of review and assessment of 1st (with the exception of nuclear fuel cycle IIRR), 2nd and 3rd category radiation facilities and the preparation of Binding Technical Report proposals that have to be approved by the Council's Plenary Meeting. As a general rule, the CSN radiation facilities organization does not have the matrix structure that is available for the Nuclear Facilities, even though the assessment or advice of specialists may be used whenever is needed.

The team was informed about the following rules in place for the training of the staff in charge of review and assessment. Newcomers undergo a selection process guaranteeing an initial training on generic nuclear safety and radiation protection. They are assigned to a specific department and receive their job training under the supervision of an experienced person for a 3 month practice period. The staff may apply for annual training sessions like CIEMAT radiation protection course, or may attend courses provided by some universities (Training course on PET by the University of Navarre) or private companies (Monte Carlo shielding calculation, management of high activity sources at Nordion) or by other competent authorities (NRC courses).

Regional executive authority inspectors in charge of review delegated by CSN must follow CIEMAT radiation protection course, 3 month training at CSN headquarters. They are placed under supervision of CSN staff during one year before a formal document of accreditation is issued, 9 out 17 regions received delegation from CSN to perform review and assessments.

The review, assessment and inspection processes are described in the set of technical procedures available. When dealing with a particularly significant, large or new applications for which there is no specific procedure, an assessment guide or programme is prepared which includes the most significant issues relating to safety and radiation protection, which must be assessed taking into consideration the predictions of the applicant. The team has been informed about such a guide being approved for a new cyclotron project.

Furthermore, the team has also been informed about an enquiry performed among licensees who gave good feedback to CSN in particular regarding its review and assessment process.

Radiation protection and dosimetry services

The CSN prepares an Annual Work Plan in which the review, inspection and control activities associated with the technical radiation protection services are developed.

Currently only two of the dosimetry laboratories are being accredited according to ISO norms by the National accreditation body (ENAC). The CIEMAT, serving as a reference laboratory for the CSN (external dosimetry, internal dosimetry, SSDL with Co-60, Cs-137 and X-ray ISO radiation qualities), will apply for accreditation this year. In accredited laboratories the assessment will consist of verification of the quality accreditation. For laboratories without accreditation the assessment also covers the QA aspects prior to authorization.

Review and assessments of modifications

In accordance with the Regulation governing Nuclear and Radiation Facilities, any modification, even if it is of small importance, is subject to a license process, which entails the assessment of the design of the

requested modification and an Inspection visit prior to its commissioning. The depth of the assessment is related to the significance and hazard associated with said modification. All this is included in the corresponding technical procedures.

As already mentioned, the new version of the RINR (Article 40) provides for different processes to process the design modifications of radiation facilities, taking into account their significance from the radiation safety point of view.

For dosimetry services, the obligation to notify the CSN of any modification of the technical and human means that were the basis for granting the license are defined in the conditions included in the authorizations.

The process of assessment and review of the technical documentation attached to the license applications of radiation facilities are commensurate with the nature and potential magnitude of the associated hazards and performed according to robust procedures. For dosimetry services, every fifth year CSN organises in cooperation with CIEMAT and the Institute for energy technics (INTE) an intercomparison of the performance of all dosimetry services in Spain, with a subsequent meeting where the results are presented, followed by letters sent to participating laboratories, informing them about results and/or requesting for improvements.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.8 states that "In *connection with its review and assessment activities, the regulatory body shall* define *and make available to the operator the principles and associated criteria on which its judgements and decisions are* based".

G3 **Good practice**: Regular meetings with Spanish radiation protection societies and the Spanish health physics society are also organized to discuss review and assessment issues.

4.2.3. Decommissioning, Waste and Remediation and Environmental Surveillance

For relevant information, see Section 4.1.3 as well as Section 8 on Infrastructure for radwaste, decommissioning and remediation, and environmental surveillance.

4.3. Development of regulations and guides

4.3.1. Nuclear Facilities

During the past years the legal system has considerably been developed in recent years (Laws 24/2005, 27/2006, 33/2007). CSN had to enforce new obligations as required by new or modified Laws and related Royal decrees. The current legal bases gives CSN all necessary means for issuing regulations and for regulating nuclear safety.

In former years CSN has based its regulatory procedures on its own mostly administrative regulations while for the technical nuclear safety matters mainly regulations and guides from the country of origin of the

design (US, FRG) were used. In recent years the Spanish nuclear safety regulators as well as the licensees were confronted with new challenges from legislation, from the electricity market as well as from the public. Major effort were launched by CSN and also licensees, partly also joint efforts promoted a CSN/UNESA Liaison committee to improve the system of regulations and guides regulatory process of related regulatory means for the interaction with the licensees to:

- Further develop the "regulatory pyramid".
- Compile the current licensing base for each plant.
- Enable continuous improvement of regulations and safety practices.

Further challenges result from the needs to harmonize with WENRA reference levels by 2010 and from IAEA standards that are continuously developed (five two six years review cycle).

Discussions with counterparts cover among others:

- Development, structure and content of the regulatory pyramid.
- Process descriptions related to the development of laws and related regulations (normativa).
- Regulatory interactions with licensees for concrete examples as involvement in new instructions.
- Programme and management of the development of instructions and guides inclding stakeholders involvement.
- Regulatory approach the licensing base.
- Evaluation of annual licensee reports on new safety requirements relevant to the license base.
- Management of new safety requirements issued by foreign institutions.
- Assessment of applicability of foreign standards (10 CFR 50 and 100) for Spanish plants.
- Standards for conditional applications of foreign requirements for license renewal.
- Projects for the harmonisation with international standards.

To suit the legal system and the additional challenges CSN is following a very pragmatic approach. First the established system of Instructions (legally binding)and Guides (recommended methods to achieve compliance) was reassessed and amended by a system of additional instruments as "Complementary Technical Instructions" (legally binding), technical instructions and different types of letters for consultation with the licensees.

All these regulatory activities are well planned and performed within the management system. An overall concept for the overall system of regulations and guides has not yet been established but is foreseen. As the processes are very flexible the system of regulations and guides can be adapted to the overall concept. The pragmatic approach enables that necessary regulations can be established without waiting for the overall concept.

This pragmatic approach has also been chosen for the WENRA action plan: for each issue an instruction will be established in accordance with the given time schedules.

The plan to establish an overall regulatory framework outlining the policy and concept as the main development lines for regulations and guides will be an important challenge for CSN as it should integrate regulations from countries of origin, from past Spanish regulations and practices as well as WENRA references and IAEA standards.

The CSN Instructions establish requirements with which all operators must comply. Each license is amended by generic "Limits and Conditions on Nuclear Safety and Radiation protection associated with the Operating Permit". These and other higher level regulations provide an adequate framework for more detailed conditions and requirements amending the individual authorizations (complementary technical instructions).

These means are now used to formally establish the current licensing base for each operating nuclear power plant by an "complementary technical instruction" in terms of applicable standards from the countries of origin of current plant designs. The current annual reports of the licensees on the significance of the development of regulations and guides in the countries of origin will in future be focussed on the licensing base laid down in the respective "complementary technical instruction".

With respect submittals for the extension of the operating license (10 years license renewal) the licensee has to consider a broader scope of regulatory documents. A set of "standards of conditioned application" has to be selected and agreed with the regulator. A four step approach is practiced to select the relevant "standards" including a systematic discussion of proposals made by the respective licensees based on regulations of the country of origin (mainly US NRC 10 CFR 50 and 100) The CSN assessment and decision making process is well based on criteria and a flow chart leading through the process towards conclusions to be submitted to the commission for endorsement.

The approach followed requires significant resources on sides, the regulator and the licensee. The team has found evidence that CSN has practiced this approach without major problems. The approach deepens the understanding of safety issues and promotes a comprehensiveness and completeness. The predictability of the regulatory activities is increased. It allows incorporating requirements into individual authorizations that take the current state of the art into account. So far backfitting activities performed in other countries than those of the origin are not taken into account systematically.

While currently nuclear safety matters are mainly addressed by safety guides now a considerable set of legally binding CSN instructions is under way, partly addressing items that are also addressed in today's guides. Some of the guides are quite detailed and sometimes might be close to prescriptive regulations without a challenge for the licensee to choose the optimal solution also from a safety point of view. In addition concrete enforcement actions are taken by "legally binding" "complementary technical actions" for the individual licensees. Both the regulator and the licensee are practicing instruments to manage these complex activities and to keep track of the impact on plant design and operation. It is a major challenge for CSN to keep the set of regulations and guides clear and concise, to ensure applicability and to strengthen the responsibility of the operator for safety. Instead of issuing guides the regulatory can also compile solutions that have been accepted from the safety point of view and by thus set references for compliance with the set of binding regulations.

The involvement of stakeholders is required by law and specified in process descriptions and related generic process schedules. Formal response to comments is required. All relevant CSN process descriptions include a systematic approach to the feedback of experience. A major effort has been decided to transfer WENRA reference levels into legally binding CSN instructions. In addition a systematic comparison of CSN regulations and guides against IAEA standards has been launched.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 § 5.25 states that "The *system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be* regulated. *Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate* time-scales."

S7 **Suggestion**: The planned CSN policy and overall strategy for the development of binding regulations and guides should be developed in the near future. It should respond to needs identified and experience made with the current activities to further enhance consistency and completeness of the Spanish 'regulatory pyramid'.

The approach should ensure that the requirements imposed by the regulator do not relieve the operator of its prime responsibility for safety.

S8 **Suggestion**: CSN should compile a uniform glossary to be used for all legally based regulatory documents. This glossary should also enable and support the proper understanding or interpretation of the respective language used in the countries of origin, as well as in IAEA standards.

(1) **BASIS**: GS-R-1 § 5.26 states that "The *main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a* framework *for more detailed conditions and requirements to be incorporated into individual* authorizations."

G4 **Good practice**: CSN practices a well based and thorough approach that requires the licensees to systematically assess advances in international standards and to take relevant standards into account and to make them binding for licensees. The practice of annual reviews of the development of safety standards related to the licensing base as well as considering additional standards and practices in the context of license renewal processes supports continuous development of plant safety.

S9 **Suggestion**: Regarding major backfittings, the state of the art of backfitting technology for comparable designs in other countries – not only the countries of origin – should be taken into account for more detailed conditions and requirements to the licensees.

(1) **BASIS**: GS-R-1 § 5.28 states: "In *developing regulations and guides, the regulatory body shall take into consideration comments* from *interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety* standards."

G5 **Good practice**: The CSN approach to keep track of the development of regulations and guides in countries of origin to take into consideration comments from interested parties and the feedback of experience is very systematic and comprehensive.

S10 **Suggestion**: CSN should address possible inconsistencies for Spanish regulations resulting from requirements from foreign sources as the countries of origin of design or the IAEA more directly. The experience made with the integration of different sources into the Spanish system of regulations and guides should be reported back for consideration by the respective institutions to promote resolution of such inconsistencies.

4.3.2. Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services

General

There is a hierarchy of laws, regulations and guides relevant for industry and medical applications. The *Law* of Nuclear energy (1964) and the Law Creating the CSN (1980) has recently been revised (2007). In the level beneath there is five *Royal Decrees* regulating nuclear and radiation facilities, sanitary protection, medical X-ray devices for diagnosis purposes, protection of outside workers with the risk of exposure to ionizing radiations due to their interventions in controlled areas, and control over sealed sources. There is also a set of *CSN regulations* functioning more like technical procedures for radiological passport for outside workers (clearance), the qualification needed to get a license for a radiation protection services, qualifications for personnel in radiation facilities to get a license, separately devoted to five categories of applications (radiation therapy, nuclear medicine, industrial radiography, laboratories with unsealed sources, Control of processes and analytical laboratories).

Still on the mandatory level there are *resolutions* from 1992 in relation to courses in X-ray needed for license to supervise/operate, and CSN is issuing *technical instructions,* both generic and specific.

On the guidance level, CSN has the capacity to issue safety guides, as established in the Law establishing the CSN (Article 2a). The CSN safety guides provide methods recommended by the CSN from the nuclear safety and radiation protection point of view and is objective is to orientate and help users on the implementation of Spanish regulations. The guides are not mandatory and the user may follow different methods to those included in the guides if they are dully justified.

The Regulatory Body develops regulations and guides in accordance with the legal system of the State and these take account of the nature and extent of the facilities and activities and practices being regulated.

Article 2 a) of the Law 15/1980 establishing the CSN assigns to the CSN the function of proposing to the Government the necessary regulations on nuclear safety and radiation protection as well as their reviews.

Likewise, said Article 2 a) establishes that the CSN may prepare and approve the Instructions, Circulars and Guides on technical issues related to nuclear installations and radiation facilities and the activities related to nuclear safety and radiation protection.

On the other hand, the amendment introduced by Law 24/2005, of the 18th of November, on the reforms to boost productivity includes a paragraph about the binding nature of the Nuclear Safety Council's Instructions once they are published in the Official State Gazette (BOE).

The CSN's Plenary Meeting Agreement, of 20th December 2000, establishes the hierarchy of CSN Instructions, Technical Instructions, Complementary Technical Instructions and Guides.

The CSN does issue regulations (CSN Instructions) and guides, although the Legislative Regulations are issued by the Ministry competent in the subject in question. At the CSN there is a Regulatory Committee in which the Ministry of Industry is represented. Therefore, there is a channel for coordinating and monitoring regulations different from those issued by the CSN.

The regulations establish the general framework that must be met in order to be authorised to perform the activities regulated in the area of nuclear safety, radiation safety and activities.

Their objective, the scope of application and the requirements that must be met by the licensees of the installations and facilities or activities are established in each of the legal or regulatory documents that constitute the regulatory infrastructure.

The regulatory framework provides for more detailed conditions and requirements to be incorporated into individual licenses. These are established in:

- The Law establishing the CSN (Article 2b, complemented with Article 2a).
- Royal Decree 1836/1999 (Articles 6.4, and 7).

In addition, each licensee must met specific conditions associated with its facility as required in the licence for operation. The Nuclear Safety Council may issue complementary technical instructions directly to the licensee in order to guarantee the maintenance of the safety conditions and requirements of the facility and better compliance with the requirements established.

The licenses granted and issued by the CSN to Entities providing Services, indicate that the CSN may modify the conditions established in its license at any time.

CSN has provided 62 Guides from which about 16 are dedicated two industrial or medical applications, or entitled services like the Dosimetry and Radiation Protection services, all provided on the CSN web.

As an addition form of guidance, abundant high quality training material in radiation protection is also provided at the web site. These are to help the facilities to prepare the applications, to say something of the needed content in courses to get license as supervisors, operators, and a powerful tool to disseminate safety culture.

In developing regulations and guides the CSN takes into consideration comments from interested parties. The legal requirement for this is included in:

1. Articles 22 to 25 of Law 50/1997, of the 27th of November, on the Government: organisation, competence and functioning (BOE of 28th November 1997). Title V, of the legislative initiative, of the regulatory authority and the control of the acts of the Government.
2. Law 27/2006, of the 18th of July, whereby the rights of access to information, of public participation and of access to justice as regards the environment are regulated, Section b) of Article 1.
3. Law 30/1992, of the 26th of November, of the Legal Status of Public Administrations and the Common Administrative Procedure.
4. PG.III.03. Points 3, 4 and 5 of Section 6.3. Additionally, regulations have been amended as a result of feedback from operators.

When developing regulations and guides, the Regulatory Body takes into account internationally recognised safety standards and recommendations such as those of the IAEA.

This is expressly required in Section c) of Annex II of CSN Procedure PG.III.03, which specifies that the accompaniment report will contain "a comparative analysis of the CSN Instruction (IS) or the Safety Guide (GS) in connection with other international standards or standards from other regulatory bodies, where appropriate".

According to the new Law 33/2007, of 7th November 2007 (Article I h) the CSN shall collaborate with other competent authorities in issues related with radiation protection of the people subjected to medical diagnosis or treatment procedures with ionizing radiation. This collaboration needs to be clarified, to be sure that the requirements in the Medical exposure directive 97/43 Euratom can be met in the overall Spanish legislation. An internal working group has already been set up on the subject.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.27 states that "Guides, *of a non-mandatory nature, on how to comply with the regulations shall be* prepared, *as necessary. The guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the* operator."

G6 **Good practice**: The material available on the CSN web site, including guides and training courses in radiation protection, is comprehensive for the various practices and is an efficient tool to contribute to safety improvements among the many operators involved in radiation facilities or using X rays for medical diagnostic purposes.

4.3.3. Decommissioning, Waste and Remediation and Environmental Surveillance

For relevant information, see Section 4.1.3 as well as Section 8 on Infrastructure for radwaste, decommissioning and remediation, and environmental surveillance.

4.4. Inspection and enforcement

4.4.1. Nuclear Facilities

Inspection

The inspections of nuclear facilities are carried out by the CSN's headquarters inspectors and the resident inspectors of the nuclear power plants. All of CSN's nuclear facilities and radiation protection divisions take part in the inspections. The 30 % of CSN's technical resources were allocated to inspections in 2006.

The regulatory framework for the inspections is defined in the Law (25/1964) on Nuclear Energy and the Law (15/1980) on the Nuclear Safety Council, Royal Decree (1836/1999) and the CSN Instruction 14 "on the resident inspectors, issued November 2007. The Royal Degree specifies the duties and the rights of the CSN. CSN Instruction 14 describes the duties and rights of the resident inspector as well as the interface of the resident inspector with the licensee. Instruction 14 was developed as CSN needs to be informed by the licensee in a timely manner of the status of the plant and its SSCs.

The objective of the inspections is to verify that the condition of SSC important to safety and the operation of the plant comply with the licence. All of CSN's inspections are described in the document "Modelo de inspección del CSN", September 2007. This manual describes the overall inspection system and is considered by CSN personnel as equivalent to management system procedures. The inspections are classified into three categories: for the first licensing inspections, for the second oversight inspections and for the third special inspections. The third type of inspections can be reactive or planned inspections depending on the type of issue involved.

The types of inspections are described in CSN procedures. Those procedures common to both technical departments are called administrative procedures and those specific to either of them are called technical procedures. The procedure (PA.IV.01) describing baseline inspections was in the draft stage at the time of IRRS mission.

Planned inspections and Periodic inspection programme of the nuclear power plants

The planned inspections of nuclear facilities consist of both authorization inspections and those associated with either the periodic oversight inspection programme for nuclear power reactors "Systema Intergrado de Supervisión de las centrales nucleares en operación" (SIC'S) or the periodic inspection programme for the nuclear fuel fabrication facility. In addition to this, there are reactive inspections resulting from inspection findings or other safety issue inputs. The authorisation inspections are generally related to the commissioning of the system or activity under review. There are 79 inspections of the six nuclear power plant units planned for the year 2008 and 16 inspections planned for the nuclear fuel fabrication facility, which will be made by CSN headquarter inspectors. There is a further plan of 19 inspections at the time of the IRRS mission covering supplementary inspections. These inspections are related to authorizations and supplementary inspections related to the SIC'S programme or safety issues such as sumps. Out of the 79 periodic oversight inspections planned for the year 2008, 78 are SIC'S inspections and one is on physical protection. The number of authorization inspections is dependent on the licence applications and their nature as well as the need for any type of supplementary inspections.

The SIC'S inspections comprise 42 different main inspections each of which includes one or more inspections made by the resident inspectors and CSN headquarters inspectors. The SIC'S inspection programme is divided into five groups. The number of main inspection procedures in each group is presented below:

- Nuclear safety 27
- Radiation protection of the public 5
- Occupational radiation protection 4
- Emergency preparedness 2
- Other inspections 3

The 'other inspections' group consists of inspection of the corrective actions programme, verification of safety indicators and investigation of events. This last inspection can be announced or unannounced. There is 3-4 unannounced inspection per plant each year.

The periodicity of the SIC'S inspections varies from quarterly to biennial. The quarterly inspections are focused on maintenance and operation of the plant and they are carried out by the resident inspectors. Four inspection procedures for the inspections to be made during outages. The scope of annual inspections is safety performance indicators, emergency preparedness and licensees' corrective actions programme. The inspections are carried out every second year by the CSN headquarters inspectors and cover all aspects of nuclear safety.

For every inspection there is an inspection plan, an observation report describing the conduct of the inspection and an inspection report where the findings are evaluated. This evaluation is performed by the inspector. In the case of possible relevant findings, an evaluation is made by a team of experts at CSN headquarters. The criteria for the evaluation process are set out in CSN procedures. The inspection observation report can have minor findings which do not go into the evaluation process. These greater than minor findings with low safety significance are classified as category "green" by the inspector. These findings trigger corrective actions which must be registered in the licensee's corrective actions programme.

The major findings are evaluated by the team of experts and classified into three categories based on the safety significance of the issue. The lowest class of major findings is "white" indicating some degradation of the safety function. A "yellow" finding would indicate multiple or repeated degradation of the safety. Finally the most severe class "red" would indicate unacceptable operation. The regulatory measures taken in response are graded in accordance with the classification as follows. For 'white' findings, the root cause analysis of the utility is performed by the plant site. A 'yellow' finding triggers an inspection to assess the occurrence of the problem at the utility. For 'red' findings, an independent root cause analysis is performed by CSN.

The SIC'S programme is characterized as a risk informed inspection programme. The deterministic and probabilistic criteria used in the SIC'S programme are:

- the safety indicators covering safety systems, barriers, radiation protection and emergency preparedness.
- out of service times, outage, risk monitor (PSA).
- PSA is used in selection of the SSC to biennial inspections design and functional integrity (PT.IV.218).
- PSA is used in the evaluation of the inspection findings (initiating events, mitigating systems), some inspections have deterministic criteria.

The probabilistic criteria cannot be applied to all of the areas and deterministic criteria are applied to safety pillars. There is a safety indicator related to the fuel integrity. In this area the findings area always "green". The licensee must take corrective actions to solve the problems found.

Quarterly the results of the SIC'S inspections and other inspections are evaluated and the plant status in different safety areas is presented. These areas are postulated initiating events, mitigating systems, barriers, emergency preparedness, radiation protection of the environment, occupational doses, physical protection and cross cutting safety issues. The resident inspector prepares a summary of his inspections together with the inspection findings and their evaluation to present at a meeting. For each of the seven areas the plant

status is indicated using the same colour coding as when assessing the inspection findings. Green colour indicates acceptable operation. However although the colour is green there can still be several minor inspection findings requiring corrective actions. The numbers of findings is presented graphically. In case of several green areas with a number of minor findings, a cross-cutting safety issue can be raised. The procedure for feedback and reactive inspections is the same as for findings. The report of the assessment is delivered to the licensee and the results are also published on the CSN web site. At the moment the initial inspection reports with licensee comments and the overall systematic assessment presented in the SIC'S information package can be found on the CSN web site. However there is no direct link in between these two sources of the same information..

The SIC'S inspection evaluation covers only inspection findings. Those review and assessment findings which are related to the initial licensed design basis of the plant may be fed to the SIC'S evaluations (PG.IV.07). However other review and assessment findings are not fed into the SIC'S programme. There is no process in place for making an integrated safety assessment of the plants which includes all the observations made in the review and assessment work and the inspection work.

In the CSN's annual report to the parliament the trends in the nuclear industry are presented.

Resident inspectors of the nuclear power plants

There is a senior resident inspector and a resident inspector at each unit. The minimum time served at a plant is three years and the maximum time is 10 years. Resident inspectors can have different professional backgrounds. The framework for regulatory control by the resident inspectors is defined in the procedure (PT.IV.09, being updated), the SIC'S procedures and the licensing documents of the plant.

The main tasks of the resident inspectors are the conduct of the SIC'S inspections, collecting information on the plant status and delivering that information to CSN head quarters, and activities related to emergency preparedness.

Planned inspections and periodic inspection programme of the fuel fabrication facility

Inspections of the fuel fabrication facility are described in an administrative procedure and the CSN inspection model. The periodic inspection programme consists of annual and biennial inspections. The programme covers safety aspects such as chemical security, criticality, fire protection, operation and organization and management, physical protection, radiation safety and functional support of the facility. All the essential areas are covered.

The inspection findings are classified via a formal deviation finding process, which was applied to all of the inspections before the new SIC'S programme was introduced.

The inspection reports are available on the CSN web site. These describe in detail the conduct of the inspection, but there is no summary of the findings and their classification. The inspection report is followed by comments from the licensee and CSN's response to these comments.

There is no overall integrated assessment of the inspection findings of the fuel fabrication facility. Only events are described in the annual report to the parliament.

There are licensing inspections, periodic oversight inspections and special inspections which cover the whole spectrum of the required inspections. The authorization requirements and thus the related inspections differ between the nuclear power plants and the nuclear fuel fabrication facility. There are also specific periodic oversight programmes designed to meet the requirements of the safe operation of these two types of nuclear facilities. There is a process in place to assess the inspection findings and take reactive inspections when needed.

The authorization inspections and the SIC'S inspections cover in general all the aspects presented in GS-R-1 para. 5.13. However there are specific training inspections (PT.IV.208), living PSA inspections (PT.IV.225) and inspections (PT.IV.224) devoted to organizational and human factors in the SIC'S programme. These three biennial inspections cover PSA and human errors in PSA, simulator training, training at the NPP and all of the aspects needed to improve the human performance at the NPP. Integrated safety management is not included due to that fact that at present there are no requirements against which the inspection could be made. These requirements will be published in near future.

The specific SSCs reviewed in the biennial inspections of design and functional integrity of the systems (PT.IV.218) are chosen by the inspectors with the help of the PSA tool. The deputy director approves the inspection plan. There is no overall long term plan or review to ensure that all the important SSC are covered during some time period. However CSN stresses that the new outcome based SIC'S inspection programme together with other regulatory activities plus the safety indicators ensures the coverage of the SSCs important to safety via the safety indicators. If degradation of the safety indicator is found, supplementary inspections will be made.

SIC'S inspection of the ultimate heat sink at the Santa María de Garoña nuclear power plant

The IRRS inspection team observed the SIC'S programme inspections on "Ultimate heat sink" at the Santa María de Garoña NPP and an operational safety inspection of the Juzbado fuel fabrication facility. At the Garoña NPP the inspection team had a short presentation on the plant by the plant deputy director and plant director. The IRRS team interviewed the two resident inspectors of the plant and verified the documentation of the resident inspector inspections.

The ultimate heat sink inspection is one of the SIC'S programme biennial inspections performed by the headquarters inspectors of the CSN. This type of inspection is described in CSN technical procedures (PT.IV.206). The inspection covers all aspects related to the design and operation of the ultimate heat sink. The inspection is a three day inspection conducted by four inspectors. The CSN inspection team consisted of four inspectors: two from the site inspection area and two from the auxiliary systems area. The resident inspectors take part in entrance and exit meetings for the inspections.

The inspection had already started on January 30th. The IRRS team observed the CSN inspection from the afternoon of the second inspection day up to the exit meeting. The team made observations on the inspection at Inspection plan point 5 "Corrective actions" and point 6 "Preventive maintenance and design modifications.

The CSN inspection team had prepared detailed questions related to the issues identified in the inspection plan. Questions were based on the review of findings from the previous inspection, event reports, inspection

reports and work orders. The two teams worked in parallel through the drawings, other related documents and representative parts of the components. The topics discussed during IRRS team visit were:

- Resolution of Zebra Mussel problem, and the Chlorine injection system installed in July 2007.
- Mobile structure cleaning problems, preventive maintenance and the visual inspection report.
- Work order on the mobile screens roller bearing.
- Vibration of the pumps in the LPCI/SW, follow-up of the previous inspection.
- Minor event report, valve failure.
- Buried pipes, their inspection results and the design modification needs.

The IRRS team observed field inspections in the control room and at the intake of the service water system. The visual inspection of the filters, pump station and the new chlorine injection system was also observed. The inspections included verification of control data for the systems. At the exit meeting, the CSN team leader presented the positive observations and observations to the licensee. The corrective actions needed due to minor findings were agreed with the licensee.

Operational safety inspection at the fuel fabrication facility Juzbado

CSN has a project manager for the Juzbado fuel fabrication facility but no resident inspectors at the site. An annual plan for the inspections is drawn up. There are 16 planned inspections for 2008, of which four are devoted to operation of the facility. Procedure (PT.IV.88), which describes operational safety inspections, was at a draft stage at the time of the IRRS mission.

The IRRS team observed part of the three day inspection conducted by the CSN project manager at the facility. The inspection topics were activities at the facility, the status of corrective actions for events in 2007, and the information on the reject fuel bundles. CSN had approved Juzbado's organizational rules on January 24th. The inspection day coincided with the first day with the revised organization. The next day a human and organizational factors expert of CSN was due to join the inspection.

The IRRS team observed the first day of the inspection. The topics included the facility and SSC status, events, the defect fuel bundles, the follow up of a safety walk made by the safety manager in the mechanical shop and the CSN inspectors' visit to the control room. The inspection was well prepared by the CSN inspector and there was a good atmosphere in the meetings between the licensee and the CSN inspectors.

The CSN inspections are planned on a yearly basis. The overall plan of inspections composes of two separate plans, one for the nuclear facilities and other for the fuel fabrication facility. Both of the periodic oversight programmes are two year programmes.

Most inspections are planned in advance. The SIC'S programme includes both announced and unannounced inspections. Most of the announced inspections are made by the resident inspectors at the nuclear facility.

CSN can assign technical support to assist the inspection. Despite this, the inspections are made by the CSN's own staff.

The plants involved in reactive inspections would be decided case by case; problems in safety systems, events, non-compliance at one plant, plant-specific issues or generic safety issues. Reactive inspections may be initiated as a result of issues raised by the resident inspector, headquarters' inspectors or national and international operational experience feedback. The scope and the content as well as the timing of the inspections are defined by the findings assessment meeting. As an example of a reactive inspection carried out in May 2007, the CSN sent a team to review the root cause analysis made by the facility after three scrams during a three days period.

All of the inspections are documented and there are processes in place to assess the inspection findings. The results of the nuclear power plant inspections are assessed systemically in the SIC'S process although for the fuel fabrication facility there is only the assessment of the inspection findings.

Enforcement

The CSN may give warnings and impose penalties on its own; it also has the legal capacity to shutdown or suspend the activities of the facility. The CSN may request from the MITYC, the imposition of economic sanctions, the temporary suspension or even the withdrawal of the license. The request for the withdrawal of the license is binding for the MITYC. The economical request is not binding for the Ministry but can be refused only for formal reasons, for example for the reason of expiration of status of limitation of violation.

In the case of non-compliance it is always required to correct the deficiency and adopt the appropriate measures to prevent its repetition. Inspections are undertaken to ensure that an operator has effectively implemented any remedial actions identified.

On finding deviations from, or violations of, legal requirements, or unsatisfactory situations which have minor safety significance, the Regulatory Body issues a written warning with a requirement for corrective actions, or directive which is signed by the General Secretary of the CSN for nuclear installations or the Radiation Protection Director for radiation protection installations directly by delegation of the Council Board. In case the licensee does not take correction actions, then penalty may be imposed directly by the CSN. The above process is only applicable to minor deviations. For intermediate and high level deviations, CSN should propose to the executive authority (MITYC or regional authorities) to initiate enforcement activities according to the Nuclear Law.

The RINR empowers an inspector and thus the CSN to stop an activity if there is an imminent risk for people. The CSN may also order the suspension of the operation or the shutdown of a facility where a situation is deemed to pose an imminent radiological hazard to workers, patients, the public or the environment.

As and examples degradation of the barriers and inoperability of the diesel generators have led to CSNs' requirement for corrective actions. One finding has been assessed as if it was 'red', launching an extensive reactive inspection programme and the exchange of information at the highest levels of the CSN and licensee organizations.

In the event of continual, persistent or extremely serious non-compliance, the CSN may order the cessation of an activity in the event of imminent risk and propose to the MITYC the temporary or definitive suspension of the license.

The discovery of ageing components in the Vandellos essential service water system was assessed in the most severe category of findings. It caused a shut-down of the plant for a longer period and remedial actions had to be taken in several areas. CSN performed extensive inspections at the plant site and a root cause analysis was made. CSN verified completion of the corrective actions before the start-up of the NPP.

All enforcement decisions are confirmed in writing to the operator. The process is documented in writing and the licensee has always the legal possibility to appeal against any type of action by the CSN or the Ministry.

Regarding on the spot enforcement actions, an inspector can force the licensee to stop an activity if it entails an imminent risk for the public or the workers, or the inspector can propose any other enforcement actions (see §5.19).

If the situation is urgent, the inspector may act directly, and if it is not, there are mechanisms for the CSN to take decisions once the licensee has informed of the situation in a period of time that depends on the seriousness of the situation.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.14 states that *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity."*

G7 **Good practice**s: CSN management of the inspections with all the documents available on the intranet across all facilities and activities is highly effective. The processes include the regular review of inspections and their findings as well as the follow up of plans with associated resources. The conduct of the inspection programmes in this area as well as others covered by the IRRS review is made in a transparent and traceable way.

(1) **BASIS**: GS-R-1 §2.6 states that *"The regulatory body shall have the authority: … [11] to communicate independently its regulatory requirements, decisions and opinions and their basis to the public; …"*

G8 **Good practice**: The SIC'S programme results are thoroughly presented on the CSN web site. The status of the utility is clearly presented and the related safety questions if any are presented in an easily understandable way. Also in-depth information can be found.

(1) **BASIS**: GS-R-1 §5.13 states that *"The main purposes of regulatory inspection and enforcement are to ensure that: [1] facilities, equipment and work performance meet all necessary requirements; …"*

S11 **Suggestion**: CSN should evaluate the effectiveness of the new SIC'S inspection programme together with the other inspection, review and assessment activities with respect to the coverage of the issues and activities important to safety.

(1) **BASIS**: GS-R-1 §5.13 states that *"The main purposes of regulatory inspection and enforcement are to ensure that: [1] facilities, equipment and work performance meet all necessary requirements; …[6] the operator is managing safety in a proper manner…"*

Recommendations, suggestions and good practices

S12 **Suggestion**: CSN should consider the balance of the resources allocated to the human and organizational issues as well as the number of inspections in which these issues are addressed. In planning inspections of human and organizational factors, CSN should also consider what is an appropriate level and way of addressing management and policy issues of the licensees.

(1) **BASIS**: GS-R-1 §5.13 states that *"The main purposes of regulatory inspection and enforcement are to ensure that: [1] facilities, equipment and work performance meet all necessary requirements; … [6] the operator is managing safety in a proper manner…"*

R1 **Recommendations**: CSN should implement a systematic way of compiling and presenting the results obtained, the trends and consequences drawn from inspections and review and assessment for all nuclear installations where applicable, and should give feedback to the licensee. This should be undertaken on a periodic basis.

(1) **BASIS**: GS-R-1 §2.6 states that *"The regulatory body shall have the authority: … [11] to communicate independently its regulatory requirements, decisions and opinions and their basis to the public; …"*

4.4.2. Radiation Facilities – Industrial and Medical Practices, Radiation Protection and Dosimetry Services

General

Article 2 of the Law Establishing the CSN establishes the inspecting function of the CSN. This Law and the Inspection Model define the different types of inspections conducted by the CSN. Radiation facilities, X-ray medical diagnostic facilities, Dosimetry Services and Radiation Protection Services and Units are also subject to inspection.

Amendments of nuclear legislation in November 2007 gave CSN additional power for enforcement. Manual (inner procedure) for enforcement processes PG.IV.06 is now under revision to implement this new power. The Law establishes different enforcement levels according to the seriousness of the licensee's deviation or infraction

Inspection

Except for dosimetry services, inspection activities in radiation facilities are partially delegated to regional governments through "Entrustment agreements". In these regions inspections are conducted by regional inspectors that are trained extensively by the CSN. CSN provides supervision of activities of regional inspectors. Such supervision is aimed at harmonization of inspection activities all over the country and includes: annual meetings, sample checks and current interaction with inspectors in regional governments. During annual meetings, results of the inspection programme are analyzed and improvements of regulatory system proposed.

The Inspection Model (manual PG.IV.04) defines the different types of inspections, their scope, and methodology. Technical procedures for inspection of different specific practices in medicine and industry that include check-lists are given in manual PT.IV.31 (inner procedure).

There is no technical procedure for the inspection of Dosimetry Services approved by the quality system, but there is a high level of staff "know-how" in this field. Dosimetry Services and Radiation Protection Services are typically inspected every three years or as required.

Facilities documentation, deficiencies, safe management etc., are explored through the CSN's inspection programme. The Law on Nuclear Energy and the Regulations clearly establishes that the licensee is responsible for the safety of the radiation facility. Informing the Inspector of the incidents does not exempt the licensee from fulfilling its obligations.

The CSN has established a planned and systematic inspection programme for radiation facilities based on annual basis. In case of limited resources, biannual frequency for 3rd category radiation facilities is allowed (categorization of radiation facilities according to the radiological risk is given in RINR). Inspection programme covers all aspects of regulatory requirements. There is a close collaboration between the CSN and the radiation protection services during inspection of the radiation facilities.

For X-ray medical diagnostic facilities there is no fixed frequency. These inspections are planned annually for 30-50 facilities in each region covering about 10% of number of facilities. The deterministic concept of risk is considered for planning programme for X-ray medical facilities – for example, relevantly high personnel doses reported to the Dose Register kept by CSN may trigger inspection of X-ray medical diagnostic facility. Additionally CSN uses "indirect" instrument of control through licensee Radiation Protection Services and Units that report to CSN about results of supervision of X-ray medical diagnostic facilities.

CSN may have joint inspections with Ministry of Industry, Tourism and Trade. Minister's inspectors do not intervene into radiation safety aspects of inspection but can realize some sanctions as representatives of executive authority – for example seal apparatus at the CSN inspector request. Up till now, common inspections have very seldom been performed, and mainly related to enforcement activities.

Inspections at the Ramón y Cajal Hospital in Madrid (31 Jan. and 1 Feb. 2008)

The team observed three inspections performed by CSN inspectors at the Ramón y Cajal Hospital in Madrid. The inspections were done at the radiation therapy unit (external beam therapy, brachy therapy), the radiodiagnostic service (in interventional radiology, computer tomography, conventional radiology, and mammography) and at the nuclear medicine department.

The inspections were conducted by two CSN inspectors according to CSN inspection procedures. The inspectors used comprehensive check-lists including for example the control of:

- Controlled area signalisation.
- Operators licence/accreditation.
- Operators training in radiation protection.
- Operators protective clothes.

- Operation logbooks.
- Maintenance & repair and quality controls.
- Contamination and dose rate checks.
- Safety equipments (TV network, interphones, emergency stop and procedures) - source inventory, source certificates of leak tests.
- Operator's personnel dosimetry/ambient dosimetry.
- Information provided to female personal in case of pregnancy.

During the inspection, the inspectors also performed dose rates and dose checks using well calibrated dosimeters.

The IRRS team found that the inspectors did their job in a very professional way; their control was apparently well accepted by the licensee. The discussions were open, good communication took place in mutual respect of both parties. The team asked the licensee if they were satisfied by the inspections. The licensee responded positively indicating that the results of the control are useful to improve the level of safety and radiation protection. Finally the team also appreciated the efforts of the Licensee to promote a good level of safety and radiation protection.

Visit to Servicios de Control e Inspeccion, S.A. (Industrial Radiography Company, 4. Feb 2008)

The IRRS Team observed the inspection of SCI by the CSN inspectors. SCI is the main vendor for Amersham QSA Global (USA) and has been authorized by the CSN for many years. The inspection was specifically undertaken among other things to assess newly constructed radiography bays for non-destructive testing using x-ray and sources, prior to an authorization for their use.

The inspection was undertaken in a professional manner and was welcomed by the licensee. A standard check list was used as a basis for the inspection and in general covered, operation and equipment logs, personnel licensees, dose records, safety procedures, information on high activity sealed sources, calibration and use of radiation survey meters, personal electric dosimeters, transport requirements, take-back agreements etc. A good safety culture was evident in the company and in many cases the safe systems of work exceeded those required by the CSN.

Visit to Ionmed Esterilizacion, S.A. (5 April 2008)

A similar good safety culture was also witnessed during the visit to the electron beam sterilisation facility at Ionmed Esterilizacion, S.A.

Inspection to CIEMAT external dosimetry laboratory in Madrid (1 Feb. 2008)

The dosimetry laboratories and radiation protection services are inspected every third year.

The team followed a regular inspection to CIEMAT external dosimetry laboratory during the mission (they also provide finger dosimetry). Two inspectors, who also act as assessors in the CSN organization and seemed highly competent and well known with the facilities, performed the inspection. They performed the

inspection in a highly professional manner, according to a dedicated CSN procedure, including review of the CIEMAT internal quality systems, the verification of certain acceptance criteria given in the license, the function of various technical procedures etc. Of particular interest was the demonstration of the CIEMAT new computer application (SIGEDO) serving both external and internal dosimetry, which was under duplicate testing with the old one. The new user interface was impressive; At a high level of confidence, the system was acceptable for the medical practitioner, the radiation protection officer, some CIEMAT staff, and also open for training and education purposes. The results from the most recent international intercomparison (EURADOS) were also reviewed.

In general unannounced inspections are conducted by CSN as reactive inspections to the complaint or report of an incident or suspicion of unauthorized activity with radiation sources. In addition, there are systematic unannounced inspections performed, for example this has been used in the inspection of gamma-radioactivity facilities.

Inspection reports can only be signed by the civil servants of the CSN. Thus, anything reported by an external consultant or expert hired by the CSN has to be approved by a civil servant and included in his/her report.

The CSN undertakes inspections at short notice. Both the Inspection Model and the reactive inspection procedures establish deadlines for conducting inspections in response to incidents / events – 2 weeks. Additionally, the CSN does not give instructions to the licensee on how to act in the event of an incident; it only supervises their subsequent actions and, in case of clear danger, it may order that the activity be ceased.

The regulation RINR requires that all inspection actions be documented through inspection reports, which are official documents with legal status. When there are findings, they are documented in specific finding reports associated to each specific inspection. In the case of radiation facilities, the findings and corrective actions are communicated in writing to the licensees.

Since 2007, inspection reports of radiation facilities and X ray facilities using medical devices for diagnostic purposes are published on CSN web-site. The only information that is excluded is information that is considered sensitive (commercial, security aspects, etc.). Even though it may have been sometimes criticized by some licensees at the beginning, this makes CSN activity transparent to public, rises public credibility and confidence to regulatory system, promote and helps to disseminate safety culture among the great number of licensees, which is much more important than for nuclear facilities.

The CSN has information technology (IT) instrument to manage safety regulation of medical, industrial and research practice. All the regulatory process (review, granting license, "licensing inspections", routine inspections, inspection findings, license amendments etc.) is managed in the framework of IT tool – Register of Installations that includes systemized safety related information and attached documentation in pdf format (application documentation, reports, license etc.)[12]. This instrument allows to control implementation of corrective actions and to analyze feed back of inspection findings into regulatory practice.

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[12] See also part 4.1.3.

The IRSS team also discussed the results of inspections performed by CSN in X ray diagnostic and radiation facilities. Each year a total of 1500 inspections are performed. The inspection report is sent to licensees following each inspection, and is published on CSN's web site, once the licensee has commented on it. CSN is probably the first competent authority giving access to inspection report for the aforementioned practices. It is a very good tool to disseminate experience feedback among licensee and the public. However, the team didn't find any evidence of public expression of the lessons learned, the trends and consequences drawn by CSN from all of these many inspections. In the report to the parliament, most of the information provided are quantitative information issued from indicators like the number of non compliances or the number of warning letters sent following to inspections.

Enforcement

The same principles described in 4.4.1 for nuclear facilities do apply for radiation facilities or X ray facilities using medical devices for medical purposes

Regarding the importance of the number of inspections performed each year in radiation facilities, CSN should give more feedback to licenses about the results, major trends and consequences it draws from these controls.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.13 states that "The *main purpose of regulatory inspections and enforcement are to ensure that [5] any lessons learned are* identified *and propagated to other operators and* suppliers…".

G9 **Good practice**: Inspection reports for radiation facilities and X ray facilities for medical diagnosis are published on the CSN web-site. The only information that is excluded is information that is considered sensitive (personal data, commercial, security aspects, etc.). This makes the CSN activity transparent to the public, raises public credibility in the regulatory system and can promote the safety of the facilities.

R2 **Recommendation**: From all its inspections in x-ray diagnostic and radiation facilities, CSN should build and express an opinion about the results obtained, the trends and consequences drawn in the different practices using radioactive sources, and to give feedback to the licensee. This should be undertaken in a periodic way.

(1) **BASIS**: GS-R-1 §5.13.states that "the *regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or* activity".

S14 **Suggestion**: CSN should consider to upgrade their internal procedures to a formal procedure for inspection of Dosimetry Services.

4.4.3. Decommissioning, Waste and Remediation and Environmental Surveillance Legislation and guidelines

The main legal basis for carrying out inspections in this area, beside the CSN Law, are the provisions of Royal Decree 1836/1999, Articles 43-46 and of Royal Decree 738/2001 on Protection against Ionising Radiations[13], Articles 65-68. The inspections carried out by CSN are further governed by general guidelines developed for,

[13] Royal Decree 738/2001, of the 6th of July, which approves the Regulation on Sanitary Protection against Ionising Radiations.

e.g., nuclear facilities[14,15] and for corrective actions in such facilities[16]. These guidelines are further developed in certain areas of waste management, including the management of spent fuel. In each case, the objective of the procedure, scope, definitions, applicable norms, responsibilities, description (how to prepare, conduct and document an inspection), references and annexes (as applicable) are described in a manual. These manuals form a stable and uniform basis for carrying out the inspections. The resident inspectors at the nuclear facilities routinely supervise radwaste (including spent fuel) management as well as other aspects of plant operation, and notify CSN of their observations, when necessary and as part of their statutory periodical reports to CSN.

The interval between inspection varies, from every two years in the case of nuclear facilities which are included in the Base Inspection Plan, to more frequent in other installations.

An inspection agenda is submitted to the installation in advance; an annotated inspection agenda is developed for the use of the CSN inspectors and serves as the basis for execution of the inspection.

The IRRS team had the opportunity to observe CSN radwaste inspections on several occasions, as detailed below.

Inspection of environmental monitoring around the Quercus Plant, Saelices el Chico, Province of Salamanca

The complex, belonging to ENUSA (ENUSA Industrias Avanzadas, S.A.) comprises uranium mining and milling facilities that commenced their activities 1974 and where, through the life-time of the Elefante Plant (1975 – 1993) and Quercus Plant (1993 – 2000), 5749 tonnes of U_3O_8 were produced. Remediation work started shortly after close-out in December 2000, and is now in a state of near completion. The objective is to "minimize *the environmental impact created during the operational phase while rehabilitating the terrain to its original* use". The pits are filled-in and covered with with 90 cm clay (obtained locally), 90 cm 'sterile' rock and 50 cm of soil. The activities also involve treatment of 700 000 m^3 of waste water per year, before discharging it into the river Águeda, a tributary to Duero.

The inspection agenda contained the following elements:

- Entrance meeting;
- Physical inspection of one upstream and one downstream water sampling station, as well as of the discharge point to the river Águeda itself.
- Physical inspection of two sampling stations for air-borne activity (filters, TLDs and Rn measurements).
- Receipt at the laboratory of samples, their stabilisation and storage.
- Documentation and related aspects.
- Exit meeting where the inspectors reviewed their main observation.

A detailed protocol, building on the CSN manual for inspections of environmental surveillance[17], had been developed beforehand, and was followed during the inspection. The dialogue between inspectors and staff

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[14] Basic Inspection Programme for Operating Nuclear Facilities. Administrative Procedure Manual PA.IV.01.
[15] Inspection and Control of Nuclear Facilities. Management Procedures Manual. PG.IV.03.
[16] Infractions and deviations identified in nuclear facility supervision processes. PA.IV.14.
[17] Environmental Radiological Surveillance Programme (PVRA). Technical Inspection Procedures. PT.IV.252.

(handling staff and managerial staff) was open but with clear consideration of the respective roles. Given the nature of the inspection (routine rather than initiated through specific concerns), the inspection was, as far as the IRRS team could judge, conducted in an adequate, structured and competent manner, and with due consideration to integrity.

Inspection of discharge monitoring at the Trillo NPP, Province of Guadalajara

As in the case described above, a detailed agenda had been developed beforehand that guided the inspectors to the process. The agenda focused on the technical content, with reference to the manual on discharge inspections[18]. The inspection considered, inter alia, documentation of malfunction of certain equipment for discharge monitoring, such as radiation monitors and flow meters, the reason for their state of inoperability and actions taken to estimate discharges (or stopping them) while the equipment was inoperable.

The inspectors verified the process of testing the one of the flow meters that monitor the two main off-gas streams leading to the stack. An unexpected problem in the verification of the calibration of the flow meter occurred, leading the management to declare the system inoperable for a few hours, while the calibration test was performed. The inspectors directly followed up the documentation of the event. Attention was also given to the monitoring of H_2 and O_2 levels in the off-gas stream, before and after the recombinator, as a matter of safeguarding against risks for explosions. The inspection was thorough, carried out in a highly competent manner, in an open atmosphere and with due consideration to integrity.

Waste acceptance at the El Cabril disposal facility for LILW (Córdoba)

Special procedure has been developed[19] for inspection El Cabril disposal facility.

The objective of the inspection was to verify the activities involved in the reception, acceptation, storage and disposal of radioactive waste.

The inspection agenda contained the following elements:

- Control of the reception of waste drums in the facility.
- Control of the acceptation of waste drums.
- Control of constitution of the Disposal Units.
- Control of compliment with the storage requirements.
- Inspection to the selected storage facilities.
- Control of the compliment with the requirements in the disposal cells.
- Inspection to the disposal cell.

A comprehensive check-list has been developed before inspection, which included all relevant data needed for the inspection. The discussion between the inspectors and staff was deep and open. The inspection has been conducted through discussion, assessment of many of the licensee's procedure and records, and visual observations.

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[18] Processing, surveillance and control of liquid an gas radioactive effluents. PT.IV.251.

[19] Waste acceptance for El Cabril disposal facility process CSN control inspection. PT.IV.15.

CSN Inspections at the Ramón y Cajal Hospital (Madrid)

The IRRS team observed inspections performed by CSN inspectors at the radiation therapy unit and nuclear medicine department of the Ramón y Cajal hospital in Madrid. The IRRS team noted the use of comprehensive check lists by the inspectors according to the CSN technical manual of inspection procedures (PT IV.31).

Among the points addressed during the inspections, verifications were performed regarding waste management. Typical items checked by the inspectors were:

- Written agreement for removal of used sources.
- Regulatory signalization.
- Access control.
- Segregation and labelling.
- Intermediate and definitive evacuation system for solid and liquid wastes.
- Evacuation criteria.
- Destination.

A control of the solid waste storage room was performed in the nuclear medicine unit. The inspectors performed dose rate measurements next to the Tc-99 used generators.

Next, a control of the therapy room and of the iodine-131 tanks connected to them in the basement was performed. The inspectors checked the monitoring system of the iodine-131 effluents present in the tanks (tank level, activities), the evacuation criteria setup as well as the overall cleanliness of this room. The controls didn't point out any deviations regarding the waste management.

Inspections in the radwaste area are carried out regularly, in a structured manner governed by defined procedures and manuals, and with competent inspectors. Earlier inspections are followed up, and results are carefully documented. From the experience gained during the mission, the IRRS team concludes that over all, the quality of work in this specific area is very high. This confirms other observations on the conduct of inspections made by the IRRS team, and reflected as a good practice also in Chapter 4, Section 4.1.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.14 states that *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity"*.

G10 **Good practice**: The CSN inspection programme for facilities for operational waste disposal and for discharge control, and the verification of the protection of the public and the environment from operating and decommissioned facilities through environmental monitoring, is highly structured, conducted in a highly competent manner, and followed up according to clear procedures.

5. Safety and security of radioactive sources

5.1. General

The basis for review of this chapter is the Code of Conduct for Safety and Security of Radioactive Sources (the Code of Conduct). Chapter 4 "Activities of the Regulatory body" of the report demonstrates provisions of the Code of Conduct; namely "Basic Principles", 'Legislation and Regulation", 'Regulatory Body" are fulfilled through the functioning of regulatory system of authorization, review and assessment, development of regulations and guides, inspection and enforcement, promoting safety culture[20] in medical, industrial and research practices.

This section[21] is devoted to the specific issues that are not covered in Chapter 4 and deal with:

- National register/inventory of radioactive sources.
- Management of disused radioactive sources.
- Services for radiation protection, safety and security of radioactive sources.
- National strategy of gaining and regaining control over orphan sources.
- Security of radioactive sources.
- Radioactive sources export – import.
- Training and information exchange.

Spain made official commitment to the principles of the Code of Conduct in April 2004. Simultaneously the Royal Decree 229/2006, of 24 February, on the control of high-activity sealed radioactive sources and orphan sources was issued to implement, inter alia, the European Council Directive 2003/122/EURATOM with the same name. Additionally to this directive, the Royal Decree includes separate article for security provisions. Therefore the implementation of the Code of Conduct in Spain was mainly achieved through the provisions of Royal Decree 229/2004, of 24 February, on the control of high-activity sealed radioactive sources and orphan sources. It should be noted, however, that high-active sealed sources are all IAEA category 1 and 2 sources, practically all IAEA category 3 sources and even some IAEA category 4 sources.

5.2. National register/inventory

Royal Decree 229/2004, of 24 February, on control of high-activity sealed sources and orphan sources establishes the obligation that the owner, who is to be authorized, keep an inventory sheet for each high-activity sealed source, including among other data the identification number of the source. The said owner

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[20] §§ 7a), 7 (b) i), 7 (b) ii), 8, (a), 8 (b), 8 (e), 8 (h), 15, 18 (a), 18 (b), 18 (c), 19 (a - f), 19 (i), 20 (c -e), 20 (h), 20 (k-n), 20 (i), 20 (p-q), 21, 22 (a-c), 22 (f), 22 (n).

[21] It should be noticed that self-assessment for the implementation of the Code of Conduct was not provided by CSN as no specific questionnaire from the Agency was available at that time. The review is therefore based on interviews and provided regulations.

is required to submit a copy of this inventory sheet, to the Nuclear Safety Council and to the Ministry of Industry, Tourism and Commerce, or to the competent authority of the regional government[22]. The CSN shall keep a national inventory of the owners of this type of sources and of the sources they possess. The form of inventory sheet is established in the Royal Decree 229/2004, Inventory sheets are provided by the licensee in four cases – acquisition, change of the location, yearly and whenever requested by the competent authority. There is no separate detailed procedure for Inventory keeping, but CSN issued complementary instruction to all the high-activity sealed source licensees explaining terms and conditions for completing the inventory sheets. Whenever the inventory sheet for a given source is closed, the identification of the new owner or recognized facility to which the source is transferred shall be immediately communicated.

At this moment Inventory is filled with initial information about the high-activity sealed source. Process of clarifying the identification numbers is under way. From the point of view of correctness and consistency of information no special checks are envisaged in the software and no reference books exist. CSN considers that this is not necessary because there are less than 700 records in the Inventory and records are kept by experienced personnel. Computer application for inventory is web based.

Information in the Inventory is checked during inspections and crosschecked between:

- User and supplier information.
- User and recognized facility to manage radwaste (ENRESA) information.

Interaction is kept with Customs for the cases of import of high-activity sealed source but there is no formal agreement between CSN and the Customs about notification of radioactive sources that have actually entered or left the country. This notification is essential for tracing purposes, because the real fact of radioactive sources entry or exit can be confirmed only by the Customs. This is applicable if the shipment comes from other than EU countries. So Customs information can be used to open or finally close the high-activity sealed source inventory sheets for "not-EU" shipments of radioactive sources.

Format of the Inventory is based on an inventory sheet that is inlcuded within the European Council Directive 2003/122/EURATOM. Thus Spanish Inventory format is harmonized with the EU countries. IAEA Regulatory Authority Information System (RAIS) is based on the IAEA categorization of sources and provides international format for national sources registers. RAIS system is used by 19 countries all over the world. Code of Conduct appeals for States to endeavour harmonization of registers formats, therefore CSN efforts for harmonization with international standard will be useful.

It should be noted that recovered orphan sources are not included in the current Inventory.

Information in the Inventory is protected[23] by access control (password), administration of graded access to the information (source user have access only to his/her own records) and administrators (4 persons have the right to make input and changes).

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[22] If the latter has functions and services transferred to it in relation to second and third category radiation facilities.

[23] Paragraph 11 of the Code of Conduct: "Every State should establish a national register of radioactive sources… The information contained in that register should be appropriately protected…"

Recommendations, suggestions and good practices

(1) **BASIS**: Paragraph 22 (g) of the Code of Conduct for safety and security of radioactive sources states: *"Every State should ensure that its regulatory body establishes systems for ensuring that, where practicable, radioactive sources are identifiable and traceable, or where this is not practicable, ensures that alternative processes for identifying and tracing those sources are in place."*

S14 **Suggestion**: CSN should establish a formal mechanism for exchange of information with the Customs about notification that a radioactive source has actually entered or left the country to make it fully traceable.

5.3. Management of disused sources

Import and/or use of any non exempted radioactive sources are authorized. CSN, before granting authorization for import and/or use of the radioactive source, assesses applications to ensure, inter alia, safe and secure management of radioactive sources at the end of its life. This assessment is based on the requirements of Article 38 (g) of Royal Decree 1836/1999 which approves Regulation on Nuclear and Radioactive Installations about facility closure. Only 2 options are allowed – return to the supplier (country of origin) or transfer to the specialized facility for radioactive waste management, the first option is preferable. If first option is not used, justification is required. For "financial" security it is required from the applicant to have financial guarantee to ensure the safe management of the source once it has become disused, even in the event of insolvency, suspension of business or any other circumstance that might affect the owner of this type of sources. This guarantee may take the form of an insurance policy, a blocked bank account or any other financial guarantee provided by a duly authorized financial institution (article 5 of Royal Decree 229/2004on control of high-activity sealed sources and orphan sources). Requirements of Royal Decree 229/2004, on control of high-activity sealed sources and orphan sources for disused source are included into license conditions in the form issued by CSN Complementary instruction. CSN inspectors check that radioactive sources are stored in the appropriate facilities and force those licensees who store radioactive sources for relatively long period of time, without intention of further use, to transfer them to recognized facilities.

If financial security measures fail to provide safe and secure management of disused sources (for the reasons of bankruptcy, disappearance of supplier, etc.) or for "historical sources" special provisions exist. According to the Article 92 of Nuclear Law radioactive material may be confiscated and secured using public funds.

Recommendations, suggestions and good practices

(1) **BASIS**: Paragraph 7 (a) of the Code of Conduct for safety and security of radioactive sources states: *"Every State should, in order to protect individuals, society and the environment, take the appropriate measures necessary to ensure: (a) that the radioactive sources within its territory, or under its jurisdiction or control, are safely managed and securely protected during their useful lives and at the end of their useful lives."*

G11 **Good practice**: Spain has established strong measures for ensuring effective management of sources at the end of their life; a condition of license that there be arrangements for return to the supplier or for proper disposal or storage, supported by financial guarantees. In exceptional circumstances confiscation of the source and its recovery from public fund is provided.

5.4. Services for radiation protection, safety and security of radioactive sources

Services for radiation safety, safety and security of radioactive sources are in place. These include, inter alia:

a) Services for searching for missing sources and securing found sources.

b) Services for intervention in the event of an accident or malicious act involving a radioactive source.

c) Personal dosimetry and environmental monitoring.

d) Calibration of radiation monitoring equipment.

More over, CSN regulate all these services in the framework of its regulatory system as described in Chapter 4 of this report. For example, in the case of radiological emergency with found orphan sources, rapid intervention is provided by ENRESA (recognized company for radioactive waste management) and contracted by CSN Radiation Protection Unit PROINSA, that have ability to reach any place in Spain in one hour after emergency notification from CSN.

Services for searching for missing radioactive sources are provided by Radiation Protection LAINSA as described in section p 5.5 below.

There are 3 laboratories for calibration of radiation monitoring equipment in Spain and one of them has the Second level of accreditation. Additionally there is a comprehensive system of services for training in the sphere of radiation protection.

In conclusion, provisions of the Code of Conduct for providing Services for radiation safety, safety and security of radioactive sources are fully implemented.

5.5. National strategy to gain and regain control over orphan sources

There is no formal document named "Strategy to gain and regain control over orphan sources" and CSN do not feel that it is necessary to have it because strategy is defined in Article 11 of HASS directive ("Orphan sources") that includes, inter alia:

- Surveillance and control, procedures for facilities and places or situations in which orphan sources may be found in accordance with the established requirements with advice from the CSN.
- Installations possibly presenting specific characteristics, such as those relating to the storage, recovery or recycling of scrap. Surveillance, control and action procedures may be carried out within the framework of agreements.
- In all cases, any person suspecting the presence of an orphan source shall notify the emergency services and CSN shall guarantee the rapid availability of specialist advisory and technical assistance services.
- Campaigns for the recovery of orphan sources arising as a result of activities performed in the past.

- Self-protection plans of each facility or activity, presenting specific characteristics, and the civil defense plans developed for radiological emergencies.

Agreements relating to the surveillance, control and procedures for action at the installations or places or in the situations in which orphan sources is most likely to appear or be processed, include the commitment of the licensees of such installations to provide training and information for their workers and measures to be taken in the event of presence of a orphan sources being detected or suspected.

At this moment there are several agreements in force and some under elaboration.

In November 1999 the Spanish Administration and the industrial sectors most heavily involved in activities relating to the recycling of scrap signed a "Protocol for collaboration regarding the radiological surveillance of metallic materials", this subsequently being adhered to by the most representative trade unions in the recycling of metallic materials. This protocol is used as a "model" in IAEA recommendations.

Each year from 50 to 100 cases are handled due to these arrangements. During the past 9 years almost 100 orphan sources in scrap metal and almost 500 contaminated materials were successfully recovered. Though the majority of orphan sources are found in scrap metal appropriate attention should be paid to other domains, where orphan sources may be found. At this moment radiation control is provided in harbours and is planned for airports.

Safety and security of orphan sources found in harbours is provided for according to "Actuating agreement in case of detection of illicit traffic of radioactive material at State harbours". Several agencies are involved – such as Ministry of Industry, Tourism and Commerce, CSN, Ministry of Interior, ENRESA, etc.

Communications with Law enforcement agencies are determined in agreement of CSN with Ministry of Interior, signed recently in 2007.

Spain has experience of national campaigns to regain control over orphan sources. For example, during the period 1980-1990 Ra-226 medical sources were successfully recovered. Now new campaign runs for 2007-2008 years period. It is funded from State budget, executed according to "Orphan Sources Recovery Plan" and managed by ENRESA. This campaign is based on the IAEA recommendations for orphan sources search (IAEA TECDOC 1388) and makes provisions for administrative and physical search of orphan sources. At this moment already 30 orphan sources are recovered with maximum activity of 5 Ci. It should be mentioned that this campaign is very well planned and organized. Search and recovery of radioactive sources is provided by Radiation protection Unit LAINSA. After 2008 the decision will be made about necessity of further search. All above mentioned demonstrates that Spain has consistent and stable policy of state recovery campaigns.

Basic Directive on Radiological Emergencies is under review now and Radiological Risk National Emergency Plan that includes countermeasures in the case of any unintended or malicious act with the radioactive sources is drafted (for details, recommendations and suggestions, see section 7 for emergency preparedness).

In the framework of Global Initiative on Fighting against Nuclear Terrorism two drills to react to radiological terrorism with the use of radioactive sources are under preparation and will take place in May 2008 (theoretical) and October 2008 (practical).

Recommendations, suggestions and good practices

(1) **BASIS**: Paragraph 20 (j) of the Code of Conduct for safety and security of radioactive sources states: *"Every State should ensure that the regulatory body established by its legislation has the authority to: ... ensure that corrective actions are taken when a radioactive source is in an unsafe or non-secure condition."*

G12 **Good practice**: Spain has a consistent and stable policy of organizing and carrying out state campaigns for restoring appropriate control over orphan sources. IAEA methodology for combined administrative and physical search of orphan sources is comprehensively implemented.

5.6. Security

As required by the article 6 of Royal Decree 229/2004 on control of high-activity sealed sources and orphan sources, along with the Physical protection plan contemplated in article 38 of the newly adopted Royal Decree 1836/1999, which approves Regulation on Nuclear and Radioactive Installations, the licensees of sources shall submit detailed information on the security measures foreseen to prevent, ensure the prompt detection of and avoid situations of loss, misappropriation and unauthorized use or transfer of sources.

Security criteria for radioactive sources are under elaboration now. Subsequent to the entry into force of these criteria, security aspects will be included into the authorization and inspection processes curried out by CSN for radiation facilities. All CSN staff dealing with practices and activities involving radioactive sources is trained through physical protection courses.

CSN programme for upgrading nuclear security in the part of radioactive sources security takes into account IAEA TECDOC 1355 and includes:

- New CSN Instruction on security criteria for radioactive sources (draft is ready).
- New CSN Security Guide on security matters for radiation facilities.
- Adapting security plans of radiation facilities to CSN criteria.

The authorizations granted shall include the limits and conditions applicable to security.

There are no trustworthiness checks for personnel and supervisors of radiation facilities at this moment.

The suggestions and recommendations for establishment of security requirements for radioactive sources and for trustworthiness checks for personnel and supervisors of radiation facilities are given in physical protection chapter. Also in this chapter such specific security issues as information protection, domestic threat and vulnerability assessment for radioactive sources and security culture are reviewed.

5.7. Export-import

Royal Decree 1836/1999, of the 3 December, which approves Regulation on Nuclear and Radioactive Installations that was revised and is d approved by Government (not published during IRRS mission) includes new provision that requires that all export-import should be made according to international agreements and commitments thus making provisions of Code of Conduct for export-import binding. Also inside EU the requirements of EURATOM Directive 1493/1993/EURATOM are used.

There is no export (return to the country of origin) of IAEA category one radioactive sources from Spain because Co-60 radioactive sources that are returned to the country of origin (exported) become, at the time of export, the IAEA category 2 sources due to radioactive decay. Import of category one and two radioactive sources is made in accordance with the Code of Conduct provisions. Concept of exceptional circumstances is not applied. No formal requirements to execute information exchange about export-import exist. All necessary actions are provided for by the Deputy Director of operational radiation protection Division, who is the officially designated contact person for export-import of radioactive sources.

In conclusion, provisions of the Code of Conduct for export-import of radioactive sources *of category 2 are fully* implemented.

5.8. Training and informational exchange

Spain has 2 neighbour States that could be affected by potential transboundary events involving radioactive sources – France and Portugal. Bilateral agreements with these countries include notification of loss of control over radioactive sources.

CSN uses established IAEA mechanism for exchange of information – Illicit Trafficking Data Base. Only loss of control or theft of radioactive sources is reported. Found orphan sources are not reported.

CSN approves training programmes for different groups of specialists that could be involved in the management of orphan sources. These groups are regularly trained.

By means of broad dissemination of information programme, CSN is increasing the awareness of interested parties about the Code of Conduct and the implications of its implementation in CSN. As the Code of Conduct is practically fully implemented (except some measures mentioned here that are under implementation) the awareness of interested parties is very high.

6. Transport of radioactive material

6.1. General

The scope of the mission with respect to the transport of radioactive material specifically refers to the activities carried out by the Consejo de Securidad Nuclear (CSN). It does not take into account the activities developed and undertaken by other competent authorities in the transport of dangerous goods.

Regulations applicable to the transport of radioactive material refer to international modal regulations for the transport of dangerous goods: i.e. ADR for road, RID for rail, the ICAO Technical Instructions for air and the IMO's IMDG Code for maritime transport, which cover the requirements of the 2005 edition of the IAEA Regulations for the Safe Transport of Radioactive Material.

In application of the functions provided in the Law Creating the CSN 15/1980, the CSN assesses the nuclear safety and radiation protection matters when approving packages and shipments. The CSN inspects transport movements, advices other competent authorities in regulation development issues and takes part in international forums on the safe transport of radioactive material. As competent authority it also provides technical support in transport emergencies. The CSN has entrusted its transport inspection duties to organizations of several Autonomous Communities. These inspections are carried out in compliance with the CSN procedures.

The CSN collaborates with other competent authorities in relation to the transport of hazardous goods through the Ministry of Public Works Committee for the Coordination of the Transport of Hazardous Goods (which develops functions related to transport activities) and also through contacts between the technical areas responsible for the inspection and control of transports.

The CSN is directly involved, acting as Spain's representative, in international forums where regulation and technical issues regarding radioactive material transport (IAEA and EU) are discussed, and has worked with the IAEA in technical cooperation activities and the development of TRANSAS missions. This direct involvement facilitates the advisory function and cooperation with the Ministry of Public Works Committee for the Coordination of the Transport of Hazardous Goods.

Regarding package and transport approval processes, the CSN carries out the safety assessment and issues a Safety Report to the Ministry of Industry, Tourism and Trade, which is the body that issues the approvals. Assessment and approval criteria take the provisions of the IAEA Regulations for the Safe Transport of Radioactive Material as a reference, and the minimum content for authorization applications is defined in a Guide issued by the CSN. Besides package and transport approval requirements, national regulations require companies carrying radioactive goods to under go a Registration process with the Ministry of Industry Tourism and Commerce.

The CSN inspects the transport activities managed by operators, as well as certain specific transport operations. The CSN defines a Basic Transport Inspection Plan on a yearly basis, specifying priority

inspections to be undertaken during that period. Other lower priority level inspections are also conducted. The inspections are carried out following internal management and technical procedures.

Given the large number of entities involved in transport activities the CSN has issued Guides and published relevant documentation to assist the operators and their staff and other authorities to control the transport of radioactive material.

The CSN provides technical support in radiological emergencies, including those that may occur during transport. Each incidence is tracked, analysed and recorded in a relevant database.

6.2. Legislative and governamental responsibilities

The principal legal provisions used to regulate the transport of radioactive material for the various modes of transport are as follows:

By road:

- Royal Decree 551/2006, of the 5th of May, whereby the operations of transporting dangerous goods by road in the Spanish territory are regulated.
- European Agreement concerning the international carriage of Dangerous Goods by Road, ADR (BOE 21/03/2007 and 11/04/2007).

By rail:

- Royal Decree 412/2001, of the 20th of April, (BOE 08/05/2001), whereby the transport of dangerous goods by rail are regulated.
- Regulations concerning the International carriage of Dangerous Goods by Rail, RID (BOE 9/03/2007).

By air:

- Royal Decree 1749/1984, of the 1st of August, which approves the National Regulations on the Transport of Dangerous Goods by Air, modified by Ministerial Order of 28/12/1990 (BOE 23/01/1991).
- Order FOM/808/2006, of the 7th of March which give effect to the Technical
- Instructions for the safe transport of dangerous goods by air (ICAO).

By Sea:

- International Maritime Dangerous Goods Code (IMDG Code), published by the International Maritime Organization, IMO. Amendment 32-04 (BOE 21/12/2005).

The IAEA Regulations for the safe transport of radioactive material (2005 Edition) are implemented for the various modes, through the implementation in Spanish legislation of the modal regulations for the transport of dangerous goods e.g. ADR, RID, ICAO Technical Instructions and the IMO IMDG Code. Transport by post is forbidden by Law 25/1964 on Nuclear Energy and transport by inland waterways does not occur.

In general terms the Royal Decree 783/2001 of the 6th of July, (BOE 26/07/2001) *Regulations on health protection against ionizing radiations,* applies to all activities with a risk of exposure to ionizing radiations, including the transport of radioactive material.

There are also regulations on physical protection, civil liability due to nuclear risks, import and export of radioactive material and performance in emergencies that apply to the transport of radioactive material:

- Royal Decree 158/95, of the 3rd of February, on the physical protection of radioactive materials.
- Law 25/1964 on Nuclear Energy.
- Decree 2177/67, of the 22nd of July. Regulations on Nuclear Liability Risk modified by Decree 742/68, of the 28th of March.
- Royal Decree 1836/1999, of the 3rd of December. This is a regulation governing nuclear and radiation facilities.
- Royal Decree 387/1996, of the 1st of March. Basic Directive of Civil Protection for planning against the risk of accidents in the transport of dangerous goods by road and rail.

The Royal Decree 1256/2003 of the 3rd of October establishes the competent authorities of the Central Administration of the State for the transport of dangerous goods and regulates the Commission for the Coordination of the transport of dangerous goods. Furthermore, the Law establishing the Nuclear Safety Council, of the 22nd of April of 1980 (Law 15/1980), defines the functions of the CSN; among them are those related to the licensing, inspection and enforcement procedures for the transport of radioactive material. The responsibilities of the CSN with respect to transport appear in the Law 15/1980.

Package approval and shipment authorisation requirements coincide with those defined in the IAEA Regulations for the Safe Transport of Radioactive Material. Additionally, there is a registration requirement for companies that transport radioactive material. This is defined in Article 78 of the Royal Decree 1836/1999 of the 3rd December governing nuclear and radiation facilities. In 2008 it is expected that this Decree will be modified among others to require only the registration of the main carrier of radioactive material. The main carrier will be required to register and assume the responsibility for any work subcontracted.

An enforcement system is included in the Nuclear Energy law (Law 25/1964) and its subsequent modifications are applicable to the practices involving radioactive material (including transport). An enforcement system applicable to the transport of radioactive material is also included in the Royal Decree 783/2001. The Law 33/2007 of the 7th November amending Law 15/1980 of the 22nd April Creating the Nuclear Safety Council updates among other things the section on infringements.

The provisions on training of workers involved in the transport of radioactive material are included in the international modal regulations applicable in Spain (IMDG, ICAO, ADR, RID) and in the specific Spanish legislation such as:

- Royal Decree 1566/1999 on Safety Advisers for the transport of dangerous goods by road, rail or waterway.
- Ministry of Public Works Order 505/2004, of the 27th February, on professional training of Safety Advisers for the transport of dangerous goods.
- Royal Decree 772/1997, General Regulations for Drivers.

Moreover, radiation facilities have to have staff with Supervisor and Operator licenses. To obtain these licenses, the relevant personnel have to attend courses approved by the CSN in accordance with CSN Guide no. 5.12. In the case of radiation facilities in which the transport of radioactive material takes place, the programme for these courses includes subjects relating to the requirements for the transport of radioactive material.

The legislative and statutory framework established to regulate the transport of radioactive material is comprehensive and covers the relevant modes of transport.

6.3. Authority, responsibilities and functions of the Regulatory body

CSN functions are specified in the Law whereby it is created, and are developed in the Statute (Royal Decree 1157/1982). In accordance with the competences defined in Law 15/1980, the CSN does not issue or revoke authorizations or approvals by itself. This function belongs to the Ministry of Industry, Tourism and Trade (MITYC), but the CSN sends Safety Reports to the MITYC in relation to the transport package approval and shipments authorization applications. In these reports, the CSN proposes the limits and conditions of the approval or authorisation. Likewise, the CSN can propose to the MITYC to revoke an approval or authorization when it deems that the nuclear safety and radiation protection conditions on which they were based originally are not maintained.

With regard to the authorities with competences in the safety of the transport of dangerous goods, there is an ongoing collaboration as regards advice, information exchange, inspection criteria, non-compliance notification and regulatory development functions. The CSN is a member of the Committee for the Coordination of the transport of dangerous goods of the Ministry of Public Works and of its corresponding Transport Subcommittees: land (road and rail), sea and air.

The CSN does not authorize external companies as such to provide technical support on its functions relating to transport. It only entrusts bodies from the Autonomous Communities to conduct transport inspections, which is known as “Entrustment of Functions”, on the basis of an agreement between the CSN and the Autonomous Administration. These Entrustments are not specific to the transport of radioactive material and affect other CSN activities.

The CSN liaises with regulatory bodies in other countries and regularly takes part in the meetings on the transport of radioactive material held by the IAEA, representing Spain within the TRANSSC Committee. The CSN also belongs to the Spanish representation in the Standing Working Group on Transport of Radioactive Material of the European Commission and the Advisory Committee on the implementation of

Directive 2006/117/EURATOM on the transfer of radioactive waste and irradiated fuel in the European Community. Likewise, it takes part in the group of regulatory bodies on the transport of radioactive material, the Radioactive Transport Study Group (RTSG).

There are general bilateral collaboration agreements between the CSN and similar bodies of other countries that also affect the activities carried out by the CSN regarding transport. There are no exclusive formal agreements on transport-related subjects. Nevertheless, CSN has collaborated in a case-by-case basis with the regulatory bodies of other countries in transport package approval processes and in the development of joint regulation and guide proposals.

The CSN issues Guides within the scope of its competencies. Those specifically applicable to the transport of radioactive material are located in Section 6 of the CSN's Safety Guide Collection.

The CSN collaborates in the training of staff from other Bodies of the State and Autonomous Communities with competencies in the monitoring and intervention in emergencies in the transport of dangerous goods: policemen, fire-fighters, civil protection officers, people in charge at ports and harbour masters. This collaboration is done at the request of the corresponding bodies. The CSN also collaborates periodically in the organization of courses with other bodies of the State (CIEMAT) aimed at transport operators (consignors, consignees and carriers).

The system in place between the CSN and the MITYC with respect to transport approvals, authorizations, registration, etc., is satisfactory.

The CSN has a comprehensive Safety Guide Collection (including leaflets and a DVD) that is specifically applicable to the transport of radioactive material. These are considered very useful for staff of the CSN, facilities and others involved in the transport of radioactive material.

6.4. Organisation of the Regulatory body

The Law Creating the Nuclear Safety Council establishes its independence from the General State Administration within the CSN's organization, the Unit responsible for the issues related to the transport of radioactive material is the Transport and Nuclear Fuel Fabrication Area (Área de Transporte y Fabricación de Combustible Nuclear – TFCN), which carries out most of the functions assigned to the CSN in this field or coordinates the execution thereof by other CSN units. The TFCN is part of the Nuclear Installations Sub-Directorate, which itself is part of the Nuclear Safety Directorate.

The resources devoted to transport activities take into account the type and number of transports of radioactive material that currently take place in Spain. However, inspection work and a future increase in licensing activities in the transport of irradiated fuel may need an increase of personnel resources.

Competences in the transport of dangerous goods are distributed among several authorities. The CSN is competent in the aspects of nuclear safety and radiation protection. Although there are no formal agreements with the rest of the competent authorities, regular contacts are maintained within the Committee for the Coordination of the transport of dangerous goods of the Ministry of Public Works and

its different Subcommittees: road, rail, sea and air. Moreover, bilateral contacts are maintained between the technical area responsible for transport at the CSN (TFCN) and the technical areas with control and inspection functions of the competent authorities for the different modes of transport: Directorate General for Road Transport, Directorate General of Civil Aviation (air) and Directorate General of the Merchant Navy (sea).

The Transport and Nuclear Fuel Fabrication (TFCN) Area includes four experts: an Area Manager, a Project Leader exclusively focused on the operation of the Juzbado Nuclear Fuel Fabrication Plant and two experts wholly dedicated to issues related to the transport of radioactive material. Within the Area, the manager and the two transport experts are in charge of: safety assessments and the issue of package and shipment licensing reports; inspection and control (including the enforcement process); regulatory development and guide preparation; relations with other competent Spanish authorities; international relations; collaboration in training; and preparation of internal procedures. All TFCN Area staff are based at the CSN headquarters. Safety assessments related to package approvals and shipment authorizations are conducted and coordinated by the TFCN Area. In order to conduct the assessments, the TFCN relies on the diverse specialist areas of the CSN, mainly: Nuclear Engineering, Mechanical and Thermal Engineering, Radiation Protection and Quality Assurance. The personnel in these areas do not perform their assessments specifically for transport matters but also provide support to other CSN areas. Their staff are also located at the CSN headquarters. In relation to carrying out inspections on transports, in addition to the TFCN Area experts, the inspectors of the CSN's Entrustments conduct transport inspections at the following Autonomous Communities: Catalonia (7), Basque Country (3), Valencia (1), Navarre (2), Galicia (1), Asturias (1), Canary Islands (1), Balearic Islands (1) and Murcia (1). These inspectors are not exclusively dedicated to transport inspection tasks; most of their work is focused on licensing, inspection and control of radiation facilities located in their Autonomous Communities. These inspectors are based in their respective regions. Transport inspections in the remaining Autonomous Communities (Madrid, Castilla y León, Castilla-La Mancha, Extremadura, La Rioja, Cantabria and Andalusia) fall under the responsibility of TFCN Area experts.

The TFCN Area is also supported in the inspection tasks by CSN inspectors that permanently reside at the nuclear power plants (2 inspectors per plant), the function of which is to monitor the operation of the facilities (including the way the transports coming in and out of them are carried out). Furthermore, the Radiation Facility Inspection Area (INRA) also performs functions of inspection of transport-related aspects; in the case of commercial and industrial radiation facilities that use mobile equipment, the inspection points thereof include those affecting the transport of radioactive material.

With respect to education and training there is an annual Training Plan at the CSN. In this Plan there are courses on subjects that are generally applicable to the functions carried out by staff with transport responsibilities and courses specifically related to radioactive material transport issues.

The only formalized tool for having contacts with operators is the Ministry of Public Work's Committee for the Coordination of the transport of dangerous goods, within which there is a Group of Class 7 Experts, made up of CSN experts and the main operators in the transport of radioactive material, in which subjects of general interest can be discussed.

The organization of the regulatory body to regulate the transport of radioactive material is satisfactory.

The establishment of Entrustment agreements with the remaining Autonomous Communities (Madrid, Castilla y León, Castilla-La Mancha, Extremadura, La Rioja, Cantabria and Andalusia) may improve the efficiency and effectiveness of the work associated with transport inspections.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §4.2 states that *"If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and co-ordinated, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator."*

S15 **Suggestion**: To support the work of the Committee for the Coordination of the transport of dangerous goods of the Ministry of Public Works, Memoranda of Understanding or equivalent should be established where possible, with the other competent authorities with competences in the inspection of dangerous goods.

6.5. Authorisation process, review and assessment

Regarding package and transport approval processes, the CSN carries out the safety assessment and issues a Safety Report to the Ministry of Industry, Tourism and Trade, which is the body that issues the approvals. This is done in accordance with Article 77 of Royal Decree 1836/1999, of the 3rd of December approving the Regulation governing nuclear and radiation facilities. The Directorate General for Energy Policy and Mines of the Ministry of Industry, Tourism and Trade (MITYC) grants authorizations for transport. Assessment and approval criteria take the provisions of the IAEA Regulations for the Safe Transport of Radioactive Material as a reference, and the minimum content for authorization applications is defined in Guide 6.4 issued by the CSN. Review and assessment principles are given in CSN safety Guides 6.1 and 6.2. Besides package and transport approval requirements, national regulations require companies carrying radioactive goods to undergo a Registration process. CSN assessments are undertaken in compliance with clearly defined internal technical procedures (PT-IV.28 and PT-IV.41) for the review and assessment of safety submissions prior to an authorization or an approval being granted. The TFCN Area prepares a technical assessment report and a binding technical report proposal (PDT) that it sends for approval to the Deputy Director of Nuclear Installations (SCN) and the Technical Director of Nuclear Safety (DSN). Once the PDT is approved, it is sent to the Plenary Meeting of the CSN, who makes the appropriate decision. If the proposal is approved, a favourable report is prepared on the application for the Ministry of Industry, Tourism and Trade, who issues an approval or authorization resolution that it sends the applicant.

The authorization process of the regulatory body to regulate the transport of radioactive material is satisfactory.

The quality of the CSN Safety Guides 6.1, 6.2 and 6.4 (published in Spanish and English) which indicate the documentation that must be submitted in order to apply for package design approvals and shipment authorizations in line with the requirements of TS-R-1 are an example of a good practice.

6.6. Inspection and enforcement

The CSN may carry out inspections related to the transport of radioactive material by land, air, and sea – focusing on the competences related to nuclear safety and radiation protection.

The CSN conducts about 60 annual inspections, which include inspections of shipments and inspections on the transport activities management by consignors and carriers. Furthermore, inspections of radiation facilities using mobile equipment (industrial radiography and soil nuclear moisture density gauges) are also undertaken under the radiation facilities work programme. Inspections may be planned, reactive, announced or unannounced.

There is a Basic Inspection Plan (PBI) for the transport of radioactive material that includes the inspections deemed essential to be conducted during the next year. The PBI is included in the CSN's Annual Work Plan and approved by the Plenary Meeting of the CSN.

Inspections of the transport activity management are also defined in the PBI of nuclear facilities in accordance with Procedure PA-IV.01. The transport inspection planning and management process is included in the Procedure PG.IV.09.

The Nuclear Power Plants Resident Inspectors must conduct at least one inspection per year on one shipment, according to the transport Basic Inspection Plan. The CSN has entrusted the transport inspection function to civil servants of the Autonomous Communities based on the agreements with these Bodies. To all intents and purposes, these civil servants act as CSN inspectors and have to apply the same procedures as the inspectors from the CSN's headquarters. The planning of their inspections is based on planning criteria defined by the CSN. In no case is the inspection function delegated to agencies, experts or consultants outside of CSN civil servants or civil servants entrusted by the CSN at the Autonomous Communities.

The experts of the TFCN Area only conduct inspections related to the transport of radioactive material. The rest of CSN inspectors that can conduct or participate in transport inspections (radiation facility inspectors, inspectors from specialist areas, entrusted inspectors at Autonomous Communities, resident inspectors of the nuclear power plants) also carry out other types of inspections.

Following an inspection, an inspection report is generated, which is sent to the licensee for comments or remarks. Upon receipt of the licensee's comments and the inspector's remarks on these comments, the document is sent to the TFCN Area where an assessment of the inspection report and the findings is conducted and, if appropriate, the enforcement process is initiated. Procedures PG.IV.09, PT.IV.30 and PT.IV.255 address the inspection of transport of nuclear substances and radioactive materials.

In the case of transport incidents and accidents, an internal (within the CSN) briefing note is immediately issued by the TFCN Area whenever an incident occurs. A report (according to a standard format) is requested from the operators (consignors, carriers) involved, which must be sent to the CSN within 10 days at most. In those cases where it is deemed necessary, inspections of the accident area and subsequently the facilities of consignors and carriers are carried out in order to conduct a detailed investigation of the event. Once all the information is available, an assessment is carried out to draw the conclusions about the event

and the lessons learnt. If the event has been of importance and significant actions – particular to the operators involved or general (affecting all operators) – have been derived from the investigations, a report on the event is issued in which the specific or general improvement actions to be adopted are included. In all cases, the events are registered in the Incident Section of the Transport Database. From this Database, a Summary Report may be generated for each event.

Regarding an analysis of the causes and consequences of accidents for 'lessons learned' there is no specific procedure defining how to disseminate the information. Depending on the case, general circulars may be issued to relevant licensees on the conclusions of an event and the lessons learnt may be published on the CSN's web page.

An enforcement system is included in the Nuclear Energy law (Law 25/1964) and its subsequent modifications are applicable to the practices involving radioactive material (including transport). An enforcement system applicable to the transport of radioactive material is also included in the Royal Decree 783/2001. The Law 33/2007 of the 7th November amending Law 15/1980 of the 22nd April creating the Nuclear Safety Council updates among other things the section on infringements. While a technical procedure for enforcement in general is available, a specific enforcement procedure for transport is being developed.

The inspection and enforcement process of the regulatory body to regulate the transport of radioactive material is satisfactory.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.17 states that "Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process."

(2) **BASIS**: GS-R-1 §6.1 In order to safely derive the benefits of the exploitation of nuclear and radiation related technologies, governments must provide for both an effective regulatory regime and an appropriate supporting infrastructure.

G15 **Good practice**: The Transport Management Database System incorporating databases on packages subject to approval, packages not subject to approval, carriers, Type B(U) packages, authorizations, inspections, and incidents and all other relevant documentation is considered to be comprehensive, user friendly and a practical management tool.

6.7. Development of regulations and guides

The CSN has legal capacity to develop and establish mandatory regulations (Council Instructions, (IS), safety guides (GS) and circulars. Guides describe the methods recommended to fulfil the regulation. The following guides exit in the field of transport.

- GS-6.01. Quality assurance in the transport of radioactive substances. CSN, 2002.
- GS-6.02. Radiation protection programme applicable to the transport of radioactive substances. CSN, 2003.

- GS-6.03. Instructions on emergencies in the transport of radioactive substances. CSN, 2004.
- GS-6.04. Documentation for requests for authorization for the transport of radioactive substances: package approvals and authorization of the shipment. CSN, 2006.

All of them are advisory in nature and represent an aid for complying with the regulations applicable to the transport of radioactive material. They are only mandatory if their compliance has been set in the conditions of the approvals or authorizations. In order to prepare the CSN Guides on transport, similar documents issued by the IAEA and/or competent authorities from other countries have been taken into account. Their development has been based on the experience in the licensing and control of transport activities.

The CSN Safety Guides on transport matters (published in Spanish and English) in line with the requirements of TS-R-1 are an example of a good practice. (See section 6.5 and the section on management systems).

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.27 states that *"Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator."*

(2) **BASIS**: GS-R-1 §5.28 states that *"In developing regulations and guides, the regulatory body shall take into Consideration, comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards."*

G16 **Good practice**: To assist all relevant stakeholders the CSN has for a number of years produced a detailed correlation table between the current IAEA TS-R-1 and the current ADR by theme, paragraph number and a comment indicating the relevant changes in each document. This pro-active approach is very practical and meets the needs of the operators, staff, etc.

7. Emergency preparedness

The requirements for infrastructure and functional requirements for emergency preparedness are given by Safety Standard GS-R-1, Legal and Governmental Infrastructure for Nuclear, radiation, Radioactive Waste and transport Safety and GS-R-2, Preparedness and Response for a Nuclear or Radiological Emergency. This section of the report assesses the role, resources and capabilities of CSN against these safety standards.

7.1. The role of the CSN

The functions of CSN in relation to emergency preparedness and response have been established by legal framework[1-4] and legal requirements have been developed through different legislative instruments[5-11] and CSN guidance. The legal basis assigns the attribution to the CSN for planning, preparedness and response, particularly making recommendations, providing advisory assistance and "…to coordinate, in all those aspects related to nuclear safety and radiation protection, the measures for assistance and response to emergency situations, integrating and coordinating the different bodies and public or private companies…"[1] in emergency matters of radiological relevance with an objective to protect workers, the public and the environment in case of radiation emergencies. CSN recommendations shall be the technical basis for decision-making at national level with regional or national level impact, or (in case of radiological emergencies) regional level referring to radiation aspects.

Emergency plans to response to nuclear emergencies are established at on site and off site levels. CSN, establishing guidance has an important role in planning and preparedness coordinating activities in this area. Activities to be performed onside the nuclear power plant are regulated by complementary technical instruction and CSN safety guide. The activities to be performed outside the nuclear power plant are regulated by the specific civil defense standards. The role of CSN in the second case is (mainly) "…to collaborate with the competent authorities in the elaboration of the criteria to which the off-site emergency plans and those for the physical protection of nuclear and radioactive installations, as well as transportation, must be adjusted..."[1]. CSN with its activities cover the whole sphere of nuclear or radiological emergencies regarding radiation related issues.

7.2. Capabilities and resources

In order to be able to carry out its response functions, CSN has established an Emergency Response Organization (ERO) complementary to its normal working organization. The ERO is the operating structure established by the CSN to undertake the corresponding functions in the event of a nuclear or radiological emergency, for which it is equipped with suitable human and technical resources and operating procedures. Technical and logistic support has been created mainly by establishing the Emergency Response Center (SALEM). Basic principles of operation of this center are given by the CSN Emergency Response Organization and Action Plan (last update in 2005). The CSN support is provided in coordination with regional (CSN) centers, what is important particularly in case of radiation accident in national level with regional impact or regional level. 24h/7d notification point is operated by CSN.

The activities of the ERO during an actual emergency situation take priority over any other CSN activity. The ERO acts independently of the regulatory and control function assigned to the CSN and has the following (exclusive) functions:

- Collaborate in taking the emergency situation to safe conditions.
- Contribute to mitigate the radiological consequences generated by the accident causing the emergency situation on people, property and the environment.
- Inform and advice the authorities in charge of directing the applicable emergency plan about the measures to protect the population.
- Inform the population about the risks associated with the emergency situation.
- Ensure compliance with the international commitments regarding prompt notification and mutual assistance as these affect the CSN.

All the means and resources required for the activities of the ERO shall be provided by the CSN from its budget and assets in accordance with the applicable budgeting and financial provisions. The Secretariat General of the CSN will provide adequate and updated procedures for urgent situations ensuring extraordinary financial means and resources necessary for the activities of the ERO.

The ERO may act in four different Response Modes (from 0 to 3). It is permanently alerted in Mode 0 through the operation of the Salem and on-call team and is activated in the other three Response Modes depending on the severity, complexity and level of the need for decision-making or duration of the emergency.

The criteria for declaration of the Response Mode in nuclear emergencies are based on the plant status and radiological consequences that might occur, the category of the accident at the facility, as established in on Site Emergency Plan (SEP), and the emergency situation declared and established in the Off-Site Nuclear Emergency Plan. The criteria for declaration of the Response Mode in radiological emergencies are based on the radiological consequences that might occur and on the category of the sources involved, as established in the Basic Directive on Radiological Emergencies (draft submitted for legal approval).

The required level of specific knowledge is reached by training of the ERO staff. The training of the CSN personnel required to intervene in the event of an emergency is a Strategic priority within the CSN overall training programme. In this respect a Specific ERO Initial and On-Going Training Plan are regularly prepared in coordination with the general CSN Training Plan. The specific plan scheduled for a year and should contribute ensuring that the different ERO operational groups and the Management are able to correctly perform their functions. The multi level training approach provides different training for groups with different level of duties during radiation emergencies including generic and position specific training. The training programme evaluation results are basis for development of future programmes. The CSN staff dealing with emergency preparedness is actively involved in training activities of first responders (“first responders” used in context of IAEA guidance) and other groups from cooperating organizations and this activity has considerably contributed to the enhancement of the level of emergency preparedness in the

country. The CSN is supporting national, regional and international cooperation and organized several events facilitating exchange of experiences in area of emergency preparedness and response (for example the ECORINTE exercise in 2007). CSN in an effort to promoting regional cooperation, and (additionally to relevant International Conventions) has strengthen cooperation possibilities in area of emergency planning and preparedness by signing an extensive agreement with French Nuclear Regulatory Authority (ASN) covering:

- Arrangements for direct notification and provision of information in case of nuclear or radiological accident.
- Providing mutual assistance in case of nuclear or radiological accident.
- Strengthening cooperation in area of knowledge development for emergency planning and preparedness.

In frame of programme implementation, CSN should consider initiating a common exercise performed in cooperation with ASN to compare protective measures for public domain in case of a transboundary nuclear emergency. Outcomes and lessons learned from this cooperation could be a basis for further regional harmonization.

Recently, a medium term maintenance and development programme for SALEM has been prepared to ensure a high degree of availability and reliability of all the supplies, equipment, communication systems and facilities, plans and training programmes necessary to perform and develop the CSN functions in an emergency. Commitment of the CSN management to allocate human and financial resources and to support activities related to planning, preparedness and response in case of a nuclear or radiological emergency creates the necessary conditions for a timely, managed, controlled, coordinated and effective response of CSN at a high professional level.

7.3. Functional requirements and decision-making in emergency situations

The emergency plans for nuclear or radiological emergencies are prepared according to the nuclear or radiation related threats and possible consequences of accidents. The requirements on structure and contents are given by regulation and CSN guidance (and new regulation on Radiological Emergencies (in approval process) and others) and Civil Protection Regulations. The new regulation on Radiological Emergencies introduces the five-threat category system identically to GS-R-2. Radiation emergencies are classified based on a system for classification (IV categories) warranting response activities, with a requirement "when notifying the authorities of an accident requiring activation of the PEN (nuclear emergency plan), the director of the PEI (site emergency plan) shall explicitly point out in which category it has been classified, including an initial assessment of the consequences of the accident and its foreseeable evolution".

CSN in an effort to have a clear allocation of responsibilities for the coordination of the response during radiation emergencies has developed written protocols defining the necessary conditions for concept of operations and operational interfaces with relevant response organizations at different levels. The CSN notification point is used for national and international notification protocols. Domestic notifications are

activated according plans or after detection of emergency by first responders in radiological emergency (police, civil defense, fire fighter, medical staff, etc.). With respect to the risk presented by uncontrolled dangerous sources in metallurgy recycling sector, special arrangement had been establish after the ^{137}Cs accident in a steel foundry in Southern Spain in 1998. The national authorities, the national Radioactive Waste Management Agency, the involved private companies, and the main trade unions drafted a protocol for preventing of and responding to such events ("The Protocol for Radiological Surveillance of Metal Recycling, a Collaboration of Government and Industry"). In case of an emergency. The internationally accepted intervention levels are bases for taking urgent protective actions. The criteria for early phase are clearly indicated in basic guidance and plans. In spite that several operational criteria are in place, a further extension of existing system based on IAEA concept for use of "OIL" (based on GS-R-2 and IAEA-TECDOC-955) should be considered, mainly with respect to interpretation of dose related values. Planning zones are adopted in the legislation and CSN is responsible for revising these zones. The technical parameters of Spanish nuclear power plants zones are identical with recommended ones by IAEA guidance (IAEA-METHODS-2003) for given installed thermal power. Conditions for protection of emergency workers are given by IS-13 and new Regulation on Radiological Emergencies. To extending the existing national guidance, CSN should consider adapting a more prescriptive guidance for group one emergency workers based on IAEA guidance (GS-R-2, EPR-METHOD-2003). Responsibilities for managing, controlling and recording doses received by emergency workers are with CSN. Establishment of an integrated network-based database system for management, control and recording of data covering also the emergency workers, enabling high level of data management presents a strong tool in emergency management. The involvement of the CSN providing radiation specialist and assessing the radiation situation is on a high level. Regional arrangements allow to ensure an adequate response in 2 hours time (over the country) at a high level of expertise, what strongly contribute to an effective emergency management at state level.

The regulatory body is in the positions to formulate recommendations for urgent protective measure based on legal basis and the new Regulation Radiological Emergencies (in approval process) and others) and CSN is the only authority having sufficient technical knowledge and expertise in the area. To facilitate interpretation of recommendation CSN staff participates in work of state level decision-making bodies with regional impact or regional level decision-making bodies (CSN representative trained for this position) and in central state level decision-making body (one representative of CSN in CECO (at Civil protection Directorate)). The role of CSN regarding the public information during a radiation emergency is established by a resolution of the Cabinet of Ministers and entrusted the CSN to providing information (in case of a need in coordination with other authorities) to the public on radiation situation. CSN web page is planned to be also used to inform public on actual status. As regarding the long term and recovery operation, CSN shall be involved in al radiation related activities and in this context, CSN should continue developing criteria and should continue participating in international cooperation in this area. Emergency waste management (for waste produced during the emergency) is ensured with Radioactive Waste Management Agency (ENRESA) under the supervision of CSN.

7.4. Exercises

Emergency exercises with participation of CSN are performed according the annual plan. For the year 2008 there are 13 exercises with different scope and scenario, mainly oriented on facilities of threat category I and

emergency situation (1) (General Emergency) or (2) (Site area emergency). After the approval of new Regulation on Radiological Emergencies CSN should consider increasing number of exercises within the annual plan for radiological emergencies enabling a broader verification of response capabilities in this field. The exercises planned for the current (2008) year are mostly oriented on early phase of an accident, there is less planning and exercise activities on late phase situations.

During the second week of the mission participation in an emergency exercise (February 5th, 2008) enabled to observe and discuss certain issues regarding the CSN training programme on emergency issues and functions of SALEM center. The technical scenario (prepared by NPP based on basic requirement of CSN following the annual plan) describes an emergency situation at Asco NPP. The most severe phase of the accident was covered by declaring general emergency. Besides of the CSN (SALEM) and NPP the national (CECO, not full composition) and regional level coordinating bodies took part simulating their decision making role. According the escalated situation the SALEM was activated to highest (3) mode. All groups of the ERO were fully involved in the exercise, analyzing and assessing the accident development. The work and actions of emergency organizations (including external organizations) clearly indicated the use of emergency plans effectively implementing the guidance developed by CSN (e.g. use of emergency classification, planning zones, recommendation (decision) based on plant status for precautionary action planning zone around the facility, readiness to prepare recommendations for protective measures based not only on prognosis, but also assessment and of radiological situation and measurements in area of urgent protective action zones and beyond, etc.) Internal (ERO) communication is maintained at high level and the effective information exchange between central, regional and technical (SALEM) center (using video conference and shared electronic logbook) is a very effective way enabling a coordinated preparation of protective measures and facilitates a prompt response in case of a nuclear or radiological emergency.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 §5.28 states that *"In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards."*

(2) **BASIS**: GS-R-2 §3.15 states that "The *nature and extent of emergency arrangements* [for *preparedness and response] shall be commensurate with the potential magnitude and nature of the* [threat]*... associated with the facility or activity."* (Ref. [10], *para. 6.4.) ... events shall be considered in the threat assessment. In the threat assessment, emergencies involving a combination of a nuclear or radiological emergency and a conventional emergency such as an earthquake shall be considered[6]. ... threat assessment shall be so conducted as to provide a basis for establishing detailed requirements for arrangements for preparedness and response by categorizing facilities and practices consistent with the five threat categories shown in Table I."*

S17 **Suggestion**: CSN should upgrade guidance on radiological emergencies to support use of the IAEA threat assessment categories.

(1) **BASIS**: GS-R-1 §6.3 states that *"...competent authorities have the necessary resources and that they make preparations and arrangements to deal with any consequences of accidents in the public domain, whether the accident occurs within or beyond national boundaries. These preparations shall include the actions to be taken both in and after an emergency."*

Recommendations, suggestions and good practices

S18 **Suggestion**: CSN should continue developing planning for *the actions to be taken* after *an emergency.,* taking into account the specific national conditions and international recommendations.

(1) **BASIS**: GS-R-2 §4.60 states that "National *guidance that is in accordance with international standards shall be adopted for* managing, *controlling and recording the doses received by emergency workers. This guidance shall include default operational levels of dose for emergency workers for* different *types of response activities, which are set in quantities that can be directly monitored during the performance of these activities (such as the integrated dose* from *external penetrating radiation). In setting the default operational levels of dose for emergency workers the contribution to doses via all exposure pathways shall be taken into* account."

S19 **Suggestion**: CSN should consider extending the existing national guidance for emergency (group one) workers by introducing a more selective specification of conditions based on IAEA EPR-method-2003 -.

(1) **BASIS**: GS-R-2 §4.62 states that "Arrangements *shall be made for taking all practicable measures to provide protection for emergency workers for the range of anticipated hazardous conditions (see para. 4.61) in which they may have to perform response functions on or* off *the site. This shall include: arrangements to assess continually and to record the doses received by emergency workers; procedures to ensure that doses received and contamination are controlled in accordance with established guidance and international standards; and arrangements for the provision of appropriate specialized protective equipment, procedures and training for emergency response in the anticipated hazardous* conditions."

G13 **Good practice**: CSN established an integrated network-based database system for management, control and recording of doses, enabling control of doses received by emergency worker. Effective management of dose records significantly contributes to an effective emergency management and protection of emergency workers.

(1) **BASIS**: GS-R-2 §3.20 states that "Large *scrap metal processing facilities, national border crossings and abandoned military or other facilities where large sources may have been used should be considered in the threat* assessment."

(2) **BASIS**: GS-R-2 §5.13 states that "Plans *or other arrangements[75] shall be made for co-coordinating the national response to the range of potential nuclear and radiological emergencies. … the arrangements should include provisions that can be used to formulate in detail a response to situations such as: a serious exposure or contamination resulting* from *contact with a source by a member of the public; the* notification *of a potential transboundary release of radioactive material; the discovery of a shipment containing a dangerous source that is not under control; the* notification *of the potential re-entry of a satellite; public concern or rumors about a threat; and other unanticipated situations warranting a* response."

G24 **Good practice**: An effective framework for managing the situation in case of uncontrolled source emergencies in metallurgy recycling sector has been established. Adaptation of the Protocol for Radiological Surveillance of Metal Recycling, a Collaboration of Government and Industry, with effective involvement of CSN, ensures a high level of readiness for this type of emergency at national level.

8. Infrastructure for radwaste, decommissioning and remediation and environmental surveillance

Radioactive waste and spent fuel emanate from a wide range of facilities including a significant number of fuel cycle facilities that are in the stage of planning, operation or decommissioning. The experience gained in Spain in this area over the years is substantial. The review in this chapter is made against mainly the criteria laid out in § 6.7 – 6.13 of GS-R-1, but also against other sections in GS-R-1, as appropriate and applicable. The main sources of information have been the material submitted by CSN during the course of preparation for the mission, the second report to the Joint Convention[24], the 6th General Waste Management Plan[25], the plan for research, development and demonstration drawn up by the ENRESA, and last – but not least – interviews with the members of staff of the counterpart and of several other organisations.

This chapter provides an overview of the infrastructure of radwaste management, used here as a collective term for the final management of all categories of waste - irregardless of origin, whether it is conventional waste or spent fuel, or whether it relates to decommissioning, remediation, clearance, discharge management and environmental monitoring – all of these aspects that in different ways relate to *public exposure.* Concluding sections under each heading summarise the stand the IRRS review has taken with regard to the subject covered, and also provide the relevant recommendations, suggestions and good practices.

8.1. Main parties

Over the years – from the commencement of uranium prospecting in 1947 up to now, a radwaste management infrastructure have evolved that currently involves as key organisations: the CSN, created through the Law 15/1980; the ENUSA (Empresa Nacional de Uranio, S.A., now ENUSA Industrias Avanzadas, S.A.), created in 1979; the ENRESA (Empresa Nacional de Residuos Radioactivos, S.A), created in 1984, and the CIEMAT (Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas), created in 1951 but having undergone numerous transformations since then; and, MITYC (Ministerio de Industría, Turismo y Comercio). Also, the utilities are part of this infrastructure as license holders, and as producers and owners of the radwaste until disposed of in the appropriate manner. All of these organisations have various responsibilities and interdependencies in developing radwaste strategies, for implementing the strategies, and for taking decisions

8.1.1. ENRESA and ENUSA

The ENRESA is the only waste management organisation of the radwaste infrastructure in Spain, although currently outside the State organisation as such and not formally a monopoly, with CIEMAT owning 80% of the shares. A change in the legal status of ENRESA is foreseen in the near future, moving ENRESA into the State organisation as a "State Business Entity", pursuant to the Law 24/2005[26] and

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[24] Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Second Spanish National Report. October 2003.
[25] Sixth General Radioactive Waste Plan. Ministry of Industry, Tourism and Commerce. June 2006
[26] Productivity Promotions Reform Act 24/2005, of 18th November.

Royal Decree 5/2005[27], thus governed by public law rather than by commercial law. The objectives and responsibilities of the new organisation will remain essentially unchanged, but more transparent with regard to the legal status of the company. The objectives and responsibilities are:

- The management of radwaste as a public service.
- The dismantling and closure of nuclear and radioactive installations.
- The drafting the General Radioactive Waste Plan (Plan General de Residuos Radioactivos, PGRR).
- The execution of those actions that are specified in the PGRR.
- The management of the fund for financing the activities of the PGRR.

The transfer of responsibility for radwaste management from the utilities to ENRESA are partially governed by law, partially by contracts set up between the utilities and ENRESA. It should be noticed that ENRESA is responsible for radwaste management, but does not assume the ownership of the waste, until its emplacement in a repository. Final radwaste management is thus a State responsibility, and after the emplacement of the waste in the repository the radwaste issue becomes a State concern in its entirety.

ENRESA is the owner and operator of the El Cabril facility (Sierra de Albarrama, Province of Cordoba) for disposal and storage of low and intermediate level waste (LILW). It is also the site for the disposal of very low level waste (VLLW), which is anticipated to be authorised shortly. In addition, some radwaste, e.g. spent sealed sources, are *stored* at the site, pending exploration of different options for their final disposal.

ENRESA also carries out the necessary research in the radwaste area, as laid out in the four-yearly plan for research, development and demonstration The current, fifth plan covers the period 2004 – 2009[28].

ENUSA carries out the dismantling of the uranium mining and milling facilities as well as the substantial remediation activities that take place on site. Furthermore, more than 20 remediation projects have been carried out to restore old uranium mines that were not operated by ENUSA. Such projects are financed through the radwaste fund of ENRESA.

8.1.2. The CSN, MITYC and CIEMAT

As for other areas, there is a strict demarcation between the CSN and the MITYC, in the sense that CSN performs the analysis, reviews, instructions and procedural developments against its background of technical competence, and issues binding reports prior to authorisations, whereas the authorisations as such are carried out by the MITYC or the Cabinet of Ministers.

MITYC has further responsibilities, which are relevant to the radwaste area, such as:

- To contribute to the definition of the R&D policy in cooperation with the Ministry of Education and Science.

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[27] Royal Decree Act 5/2005 of 11th March, on urgent productivity promotion reforms and Government procurements improvement.
[28] Plan de investigación, desarrollo tecnológico y demonstratción para la gestión de residuos radioactivos, ENRESA, 2006.

- To follow up international commitments endorsed by Spain.
- To manage the relationship with international organisations specialised in nuclear energy.

CIEMAT provides technical support in a number of areas that relate to radwaste and public exposure, such as development of analytical and software tools for assessing the migration of radioactive substances in the environment. CIEMAT is also part of the national network of approximately 20 laboratories nationwide, that perform certain services (e.g. measurements of environmental samples, intercomparisons, TLD-based environmental monitoring) to CSN, in accordance with agreements between CSN and the laboratories.

With regard to infrastructure of radwaste management, the Spanish system includes well-defined interactions between a number of organisations, each of them with clearly specified obligations. There are legal and organisational provisions in place to secure the development of policies and strategies as well as their implementation, and to raise funds that are adequate to cover the estimated cost for the final management and eventual disposal of radwaste. Spain has though entrusting ENRESA with both mandate and obligations in the final stages of radwaste management, made a clear statement as regards the responsibility of the State for the long-term protection of human health and the environment from any harmful effects resulting from the disposal of radwaste.

8.2. Strategic plans - The General Radioactive Waste Management Plan (PGRR)

8.2.1. Preparing the PGRR

The main strategic document in radwaste management is the PGRR. The document considers the generation of radwaste, the courses of action, and the economic and financial aspects (financial aspects not being studied as part of this review). The current PGRR is the sixth, approved by the Cabinet of Ministers on 23 June 2006, the first being approved by the Cabinet in 1981. The elaboration procedure is prescribed in Law 24/2005 and Royal Decree 1349/2003[29]. The procedure involves the development of the PGRR by ENRESA every four years, which is submitted to, and reviewed by, the MITYC. After approval by the MITYC, the PGRR will be subject to extended hearings and consultation, where CSN is one of the parties involved, together with representatives of industry, regional governments, NGOs, and the general public. Following revision, as needed and as appropriate, the PGRR may subsequently be approved by the Cabinet of Ministers.

8.2.2. Waste classification of the PGRR, exemption and clearance

The plan includes a purely management-oriented classification of waste, that is relevant to the waste streams (see further Section 8.2.3) and disposal options. Thus, the classification identifies:

- Low and intermediate level waste (LILW) as waste containing mainly beta- and gamma emitters, with a half-life of 30 years or shorter and with low content of long-lived radionuclides. This material is primarily intended for the El Cabril Facility.

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[29] Royal Decree 1349/2003, of 31st October, on regulation of ENRESA activities and funding.

- Low level long-lived waste: includes mainly the waste resulting from the production of uranium concentrates, for which the foreseen final management is stabilization *in situ*.
- Very Low Level Waste (VLLW), with radioactive content greater than the clearance level, that will be sent to a specific disposal area also located at the El Cabril site.
- High Level Waste (HLW), which includes radwaste with activity concentrations of alpha-emitting radionuclides in excess of 0.37 GBq per tonne, and with half lives from 30 years up to tens of thousand of years. This waste consists basically of spent fuel and other HLW. The category also includes certain ILW that in view of the specific characteristics cannot be disposed of under the conditions established for El Cabril. Such waste is foreseen to be stored in a centralised storage facility and subsequently to be disposed of in a deep geological repository.

Before the issuance of Law 33/2007, there were no specific requirements in the Spanish law obliging the producers of low and intermediate level waste (LILW) to minimize the amounts produced. The principle of minimization in production has, however, in practice been promoted by the CSN through requirements for action applied to ENRESA in relation to optimum use of the capacity of the El Cabril disposal facility.

The interdependencies among the all steps in the generation and management of radwaste are addressed through the PGRR. The evaluation process that the CSN carries out on this subject is aimed to review the consistency of the different processes and actions decided or planned by the license holder in the radwaste area.

The PGRR also considers the management of radwaste that emanates from incidents of various types. Of particular relevance here is the incident in 1998 in the Acerinox steelyard and melting facility, located in Algecíras, Province of Cádiz. The incident involved the melting of a high level radioactive source of Cs-137, that was processed due to it being included in a batch of the metallic scrap used in the process. As a result of this incident, ENRESA has removed approximately 2 500 m^3 of radwaste from the site, and transferred it to El Cabril where it is currently stored pending its final disposal.

Also as a result of this incident, the national authorities promoted initiatives to prevent further incidents of this type. The first result was the signing, in November 1999, of a "Protocol" for voluntary collaboration between the different "agents", involved in one way or the other in the matter. Since the signing of the Protocol, there has been a significant number of detections of radioactive material contained in or accompanying metallic materials of various types, and ENRESA has undertaken their removal and corresponding management.

Outside the classification into the above waste categories are materials that have been exempted from the regulatory control, or removed from the classification by the procedure of clearance. As regards exemption values, by activity or activity concentrations, these are specified in the Royal Decree 1836/1999, and supplemented by the CSN in Instruction IS-05[30].

For nuclear installations, clearance requires special authorisations in each particular case. Nuclide-specific clearance levels for different waste streams, as recommended by the EC and the IAEA, are applied. In

[30] Safety Council Instruction IS-05, of the 26th of February 2003, defining the values for exemption for nuclides as established in Tables A and B of Annex I of Royal Decree 1836/1999.

specific cases, where such recommendations are not applicable, a special analysis is made which take into account the relevant scenarios with regard to future handling and exposure pathways. In this regard, the CSN has encouraged the nuclear sector to request the authorisation of what has been termed "Common Projects" that facilitate the clearance of the more common residual materials in the NPPs (resins, activated charcoal, used oils, scrap metal, wood). The utilities will apply for a clearance authorisation to MITYC, and the CSN would need to provide a favourable report before MITYC can authorise the clearance.

For radiation facilities the Order ECO/1449/2003 establishes, with a general scope, the clearance level to be applied by the licensee and the requirements for conducting radwaste management.

8.2.3. Waste streams covered by the PGRR

Radwaste is generated by a range of installations distributed throughout the country, which use radioactive materials and substances in accordance with the specific applicable standards. Radioactive waste may also occasionally be generated in other areas as a result of specific activities. The PGRR defines the strategies for management of all radwaste. The current and potential sources and waste streams considered in the PGRR are as follows:

- *Operation of NPPs.* All operational radwaste is stored on site and then disposed at the El Cabril disposal facility for solid low- and intermediate level waste. All spent nuclear fuel is stored in spent fuel pools or - in the case of the Trillo NPP - in a dry storage facility on site. A centralized storage facility for spent fuel and long-lived radioactive waste is planned for 2010 (now delayed to, presumably, 2013), that cannot be sent to El Cabril, and for all reprocessing wastes returned from abroad.

- *Dismantling of* NPP's. Large quantities of radioactive waste are generated during decommissioning, mostly very low level waste (VLLW). In 2003, ENRESA requested a modification of the El Cabril facility for the construction and operation of a very low level waste disposal area. The design of the barriers is based on the technical requirements of the European Union for the disposal of hazardous wastes. This installation is currently in the licensing phase, with an authorisation being expected shortly.

- *Operation of the Juzbado Fuel Assembly Manufacturing Facility (Province of Salamanca).* The operation of this facility generates relatively small quantities, in the order 10 m^3 per year, of LILW that is stored and then disposed of at El Cabril.

- *Dismantling of the Juzbado Facility.* Dismantling of this facility might give rise to approximately 10 m^3 of LILW.

- *Radwaste generated at* CIEMAT, *and waste* from *dismantling of research reactors.* The operation of CIEMAT has generated a variety of 'historic'wastes as the result of the nuclear energy development programme in Spain. It is expected to generate around 900 m^3 of waste, nearly all as LILW or VLLW. Significant amounts of radioactively contaminated soils might also be generated, the volume of which will depend on the characteristics and type of the interventions required, which are still pending. Waste generation from dismantling of research reactors has been limited to some 10 m^3 of LILW.

- *Radwaste* from *radiation facilities.* These quantities (40 m^3/year) are relatively small compared to those from other sources. All waste is transferred to El Cabril for disposal, or storage in the case of spent sealed

sources. Waste arising from collection and disassembly of ionising smoke detectors are managed as waste from electrical and electronic equipment, in accordance with EU Directives.

- *Radwaste* from *incidents.* Waste arising (minor volumes) from occasional incidents, either at the regulated facilities or as a result of the presence of radioactive sources and other radioactive materials at facilities or in activities not controlled by the regulatory system. In these cases the wastes generated are almost exclusively LILW and VLLW.

- *Secondary radwaste* from *the operation of El Cabril, the central storage facility for spent fuel and HLW and other facilities.* This category comprises secondary waste, generated during the operation of these facilities, and the operation of the final disposal facilities for spent fuel and HLW. Furthermore, the management of the headers removed from radioactive lightning rods belongs to this category. All of these wastes arise in minor quantities and are LILW, or occasionally ILW.

- *Radwaste* from *reprocessing abroad of spent fuel* from *Spanish* NPP's. The volume and origins of these wastes are as follows: 13 m^3 of vitrified HLW and 666 m^3 of ILW from reprocessing in France of the spent fuel from Vandellós 1, currently stored in France and to be returned to Spain as from the year 2010, and also small quantities of fissionable materials (U and Pu) recovered during the reprocessing of the fuel from the Santa María de Garoña NPP, sent to UK prior to 1983 and eventually to be returned to Spain for management. This waste will be stored in the central spent fuel and HLW storage facility, awaiting a final solution.

- *Radwaste* from *uranium mining.* No uranium mining currently takes place in Spain. Spain has, however, produced substantial quantities (of the order of 75 million tons of mining tailings and some 14 million tons of tailings from processing), which require specific management actions. All of this waste will be stabilised and disposed of at the mining sites.

The Royal decree 783/2001, Article 56, requires the licensee to maintain records of each waste package generated and stored in the facility, containing the relevant information associated to the radioactive waste. Reporting to the regulatory authorities of quantities and type of waste generated in the nuclear and radiation facilities is established by Royal decree 1836/1999 (Art 73) thorough monthly and annual reports and is also normally required in the authorisations of nuclear facilities as annual report of activities associated to Waste Management Plans. There are no legal provisions for a centralized national waste inventory including existing and anticipated waste. It has been pointed out to the IRRS team that the CSN as well has identified this as an item for future improvement.

The PGRR forms a strategic basis for developing the actions, and for financing them, over a foreseeable period of time, with due consideration to the interdependencies between different management options. It is being regularly updated with regard to waste streams, as a renewed basis for deciding on course of actions and their financing However, it appears that the technical competence of the CSN is brought in unnecessarily late in the process of approval of the PGRR, following – and not before – the scrutiny of the PGRR by MITYC. It would appear more logic that the CSN review of the PGRR is made available to MITYC *before* the approval, to support the Ministry's review with CSN's technical competence, as suggested below. It has been pointed out to the IRRS team that the CSN as well has identified this as an item for

future improvement. The infrastructure may also be more clearly organised with regard to requirements to assess and report radwaste inventories.

Recommendations, suggestions and good practices

S18 **BASIS**: GS-R-1 § 6.7 states that "...national policies and implementation strategies for the safe management of radioactive waste shall be developed...These strategies shall take into account the diversity between types of radioactive waste and shall be commensurate with the radiological characteristics of the waste..."

G15 **Good practice**: The national system involves the obligation of ENRESA to draw up the General Waste Management Plan (PGRR), which cover all waste streams and also incorporates the views of different affected parties in the establishment of the national strategies. The PGRR is a comprehensive document that allows for assessment of interdependencies and priorities.

(1) **BASIS**: GS-R-1 § 3.2 (11) states that *"...the regulatory body... shall advise the government on matters related to the safety of facilities and activities;"*

(2) **BASIS**: GS-R-1 § 3.4 states that *"The regulatory body shall co-operate with other relevant authorities, advise them with information on safety matters in the following areas, as necessary:...(4) radioactive waste management (including determination of national policy)."*

S20 **Suggestion**: CSN should work towards, and the Government should consider, adjusting the procedure for approval of the General Radioactive Waste Plan, or PGRR, so that the plan is submitted to the Ministry of Industry, Tourism and Commerce (MITYC), together with a technical review of the safety- and radiation protection- related matters of the same document by the CSN, to assist the Ministry in judging the technical considerations underpinning the strategy laid out in the PGRR.

(1) **BASIS**: GS-R-1 § 6.11 states that *"Government shall ensure that the regulations provide for establishing and inventory of existing and anticipated waste,..."*

S21 **Suggestion**: The CSN should work with the Competent Authorities to regulate the establishment and maintenance of a national centralised inventory of existing and anticipated radwaste, including also waste that could be generated outside regulated facilities.

8.3. The El Cabril LILW disposal facility

8.3.1. General aspects

For details of the conditions for authorisation, see Section 4.1.3.

As mentioned earlier, the El Cabril facility is designed to host the LILW generated in Spain from essentially all activities generating such waste, as well as VLLW resulting from, inter alia, decommissioning in a special area on site, which is presently under authorisation. Auxiliary facilities include waste treatments systems, compactor and incinerator. Having been conditioned in its cement matrix, the waste is transferred to the disposal container. Once the container is full, it is transferred in several steps to the mortar injection station. It then returns to the container shed where it remains until the mortar has completely solidified.

On completion of the process the container is transferred to the disposal platform. The LILW facility has a disposal capacity of some 50 000 m^3, out of which currently 53% are occupied.

Specific waste acceptance criteria apply for the disposal of radwaste in the El Cabril facility, developed by ENRESA[31]. In addition to receiving waste for disposal, that are complying with the waste acceptance criteria, the El Cabril facility has two sets of installations that are used for the *temporary storage* of solid waste. The "modules" are three buildings built during the 1980's for temporary storage, located at a distance of some 1800 m from the final disposal area. Each has a rated capacity for 5.000 drums of 220 litres each. At present the process of acceptance of the stored units produced before 1992 is ongoing, the aim being for them to be transferred to the cells once compliance with the acceptance criteria has been verified. These installations are also used to store heterogeneous and special wastes, not suitable for disposal in El Cabril, pending their subsequent treatment for final disposal.

The first VLLW disposal cell at El Cabril has already been constructed. The total volume of VLLW expected with the present Spanish nuclear programme is 120 000 m^3 including the decommissioning waste from the existing nuclear installations. The capacity of the facility is 130 000 m^3. The safety assessment is similar to the current safety assessment of the operational LILW disposal facility and covers the operational and post-operational phases. The scenarios analysed include both current and anticipated events, ranging from events associated with normal evolution of the facility to less probable events. In a preliminary step of the development of the concept, ENRESA proposed, and CSN approved, a set of Basic Design Criteria. A major part of these criteria is an adoption of the technical requirements in the Spanish regulations on disposal of hazardous waste, based on the corresponding European Directive.

The facility also possesses temporary storage capacities for spent sealed sources that may not be disposed of at the El Cabril facility, and for which the definitive disposal route foreseen is deep geological disposal. The licensing of temporary storage facilities was performed in the frame of disposal facility. The waste acceptance criteria for storage are part of the technical specifications for the disposal facility[32].

The El Cabril facility is a cornerstone in the Spanish system for final management and disposal of radwaste. Its capacity is adequate for accommodating the foreseeable generation of radwaste, provided the national policy with regard to nuclear energy remains unchanged, with the exception of spent fuel and other HLW and some particular ILW. Design, maintenance, and waste acceptance criteria are, as far as the IRRS review has been able to address them, commensurate to the hazard and adequate for the purpose of public protection.

8.4. The system for management of spent fuel and high-level waste

Spent fuel management in Spain, as well as management of some other HLW, is constrained by the absence of a final solution for the disposal of the waste, as well as by the absence of a central interim storage facility for such wastes. As of now, spent fuel generated through the operation of the NPPs is stored on site, in the reactor storage pools. The progressive saturation of the storage pools have prompted a number of actions to

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[31] Criterios de acceptation de unidades de almacenamiento, Enresa, Rev. 0, Enero - 04.

[32] CSN, Autorizacion de explotacion de la instalacion de Sierra Albarrana (El Cabril), Madrid, 5 de Octubre de 2001.

alleviate the problems, such as re-racking of the fuel to a more compact storage matrix. Saturation of the storage pool already occurred at the Trillo NPP, leading to a modification of the plant to include a facility for dry storage of fuel. This solution is also currently under authorisation for the José Cabrera NPP, as a result of the ongoing decommissioning of the plant. Plans are developed to centralise the storage of spent fuel, as well as of some more HLW. There is some urgency in this, as in 2010 Spain will receive, from France, reprocessing waste originating from Vandellós 1.

The original intention was to have the central storage facility in operation in 2010, to accommodate for, and not having to pay extra for, the reprocessing waste from Vandellós 1. This is now more likely to be possible only in 2013. The conceptual design, as already on a provisional – but binding – basis is approved by the CSN, is relatively simple, in most regards passive, and with implementation of French and US safety regulations and guidelines, as appropriate. The normative issues have been agreed between CSN and ENRESA.

Siting of the central storage facility, designed for 100 years and with an operating life-time of 60 years, need to take into consideration factors like seismic activity and flooding, as well as migration of radionuclides in the environment, while still bearing in mind that this is a fairly simple design. Siting is foreseen to start in the spring of 2008, organised by MITYC. This would involve the voluntary signing up to the process by interested municipalities, and the final decision by the MITYC on the basis of availability of candidates and technical feasibility. A ministerial order of monetary compensation will apply to the selected site municipality.

In the case the creation of the central interim storage facility is unsuccessful; more NPPs will gradually have to go into dry storage. Also, decommissioning activities, e.g. for the José Cabrera NPP, can not be brought to completion, as spent fuel and HLW will still need to be stored on site.

The target year for having in operation a final repository for spent fuel and other HLW is 2050. Although other options (reprocessing, other designs) have not been definitely ruled out, the planning focuses on the construction of a deep geological repository, 600 m or more below the surface, with horizontal emplacement of canisters in disposal tunnels. Host formations considered are, or have been, salt, clay and granite, out of which only clay and granite remain viable options today.

According to the PGRR currently in force, the target year 2050 and the conceptual design can be regarded as reference points for calculation of foreseeable costs, and – therefore – for the generation of the waste management funds. The siting process, going on between 1986 and 1996, has been abandoned. However, ENRESA, through national activities and international collaboration, participates in the R&D governing SF/HLW management, as laid out in the plan for research, development and demonstration developed by the company.

In common with several other countries with major nuclear power programmes, there is no final solution for the disposal of spent fuel, as well as some other HLW, in Spain. The management of spent fuel is also constrained by storage capacity. It seems that the current activities to site and build a central storage facility can solve some of the immediate problems, although it has to be emphasised that this is an *interim* solution. Regarding the final solution, the involved parties follow, and take part in, international development and

collaboration. However, it would appear that both the knowledge in the area and the need for a solution justify a more pro-active approach to the final disposal problem.

Recommendations, suggestions and good practices

(1) **BASIS**: SF-1 § 3.29 states that *"Radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmental friendly solutions for its long term management..."*

(2) **BASIS**: GS-R-1 § 2.2 states that *"...the following requirements for the legislative and governmental mechanism of the States:... Adequate infrastructural arrangements shall be made for decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste".*

(3) **BASIS**: GS-R-1 § 6.7 states that *"Radioactive waste generated in nuclear facilities and activities may necessitate special considerations, particularly in view of the long time-scales..."*

R3 **Recommendation**: CSN should work with other competent authorities to encourage the development and communication of plans for final disposal of spent fuel and HLW, and contribute to setting the appropriate targets and conditions that would, from all points of view, govern the process, so that there is no unnecessary delay in the solution of the problem, and that also gradually would improve the estimates of future costs for the final radwaste management.

8.5. Decommissioning

8.5.1. General aspects

There is substantial experience accumulated in Spain regarding decommissioning of a variety of facilities, including nuclear reactors (Vandellós 1 and Jose Cabrera, in late and early stages of decommissioning, respectively), research facilities (e.g. the CIEMAT facilities in Madrid) and uranium mining and milling sites (no less than 24 sites restored, one under restoration). For NPPs and other installations, a procedure has emerged in which the parties directly involved (normally the utility and ENRESA) set up the contractual terms for carrying out the technical operations. CSN is informed about the arrangements but does not become directly involved until the authorisations stage, which is dealt with in more detail in Section 4.1.5 of this report. It is also worth noting that a group is being set up that involves the CSN, ENRESA, MITYC and the utilities, to take stock of the experience gained from the different projects that may provide input for development of future guidelines.

It is worth pointing out that the procedure has allowed for decommissioning activities to commence, and terminate, within a relatively short time after closing the facility. The time-line for the decommissioning of a NPP would start with the basic studies, which after – typically - a year results in a dismantling and decommissioning plan as well as a spent fuel plan (note that in the absence of a centralised storage facility, spent fuel will still have to be stored on site, *cf* José Cabrera NPP). Another three-year period is foreseen to develop these plans as well as the Environmental Impact Statement, the relevant documentation as requested by the European Union (e.g. pursuant to Article 37 of the Euratom Treaty), followed by, and communication of, a decision to shut down the facility. Further development of the mandatory documents

as specified in Royal Decree 1836/1999 occurs parallel to the transfer of responsibility from the operator to ENRESA. The time required for carrying out all decommissioning activities from the termination of the operational phase to the Declaration of Closure by the MITYC could be well below 10 years.

Decommissioning activities in Spain can in many areas serve as international benchmarks. The procedural arrangements, involving the different steps and the distribution of responsibilities between different parties is well established and mature. Decommissioning activities are carried out within a reasonable time-frame. The existence of the El Cabril LILW repository facilitates the process, as will the VLLW repository provided it becomes authorised. On the other hand, spent fuel and HLW management is hindered by the current absence of a central storage facility, which – as in the of the José Cabrera NPP – will lead to the continuing dry storage on site of spent fuel and HLW, until a storage facility can be brought into operation.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-1 § 2.2 (6) states *"Adequate infrastructural arrangements shall be made decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste."*

G16 **Good practice**: In the area of decommissioning of nuclear power plants and other fuel cycle facilities, an infrastructure has developed and matured over the years, including regulatory experience, that allow decommissioning projects to be carried out efficiently and with minimal delays. This may serve as an international benchmark.

8.6. Discharges and environmental surveillance

8.6.1. General aspects

From the point of view of public exposure from waste generated in nuclear and radiation facilities, general provisions are in place as laid out in Royal Decree 781/2001, on sanitary protection against ionising radiations. This Royal Decree in effect incorporates into Spanish legislation Council Directive 96/29/Euratom, the so-called 'EU BSS'. The Council Directive, in turn, builds on the 1990 Recommendations of the International Commission on Radiological Protection (ICRP). Thus, Article 4 refers to the principles of justification, optimisation and dose limitation, Article 6 to dose restrictions that should be applied following the guidelines issued by the CSN, and Article 13 to the dose limit for members of the public of 1 mSv per year. Furthermore, Articles 52 – 53 specify 105 requirements on discharge limitation and calculation of doses to the public, Article 57 on storage of radwaste. Finally, Article 57 specifies the obligations of the title-holder in the aforementioned aspects.

Facilities discharging radioactive substances to the environment, either these are nuclear facilities or radiation facilities, are subject to discharge authorisations as well as to requirements to carry out environmental surveillance, when appropriate. The details of authorisations are dealt with in Section 4.1.5. of this review.

For NPPs, estimated (conservatively) doses to individuals of the public do not exceed 1 – 3 microSv per year. Also realistic dose assessments are performed on an annual basis according to Aricle. 53, Royal Decree

708/2001. The inspection programme is commensurate to the hazard posed by the discharges, with normally biennial inspections. However, discharge data are scrutinised monthly, relative to 'reference levels' of discharges that are typical for adequate performance and handling of the discharge limitation systems, and which are just a fraction of discharge limits. Exceedance of such reference level would prompt the CSN to request explanations and, if appropriate, actions.

The environmental monitoring programme is based on the preliminary site description and is, for a NPP, in operation already 2-3 years before start of operations at the facility, to create a baseline for subsequent benchmarking. Programmes may (most certainly will) change according to the different stages of the life-cycle of the plant. The programme includes sampling of air, surface water, rain water, foodstuff, milk, sediment, etc., and indicators like algae, plant and fish. Sampling frequency varies depending on the type of sample (continuous for air and surface water, every tow weeks for drinking water and milk, monthly for rain water, quarterly for gamma dose rate, twice a year for sediment, indicators organism, meet and eggs, once a year for soil and vegetables). The project is according to Technical Specifications regularly revised to take into account changes in land and water uses and exposure pathways. ET also require and analytical quality control programme. In addition, CSN implements independent monitoring programmes around facilities. Some results are included in the plant monthly report and the overall data are sent in the annual environmental report required. Off site dose calculation manual establishes Reporting Levels for activity concentrations in environmental sample, derived from the discharge limits, that if exceed a report must be sent to the CSN.

Nationwide monitoring of activity levels in drinking water and foodstuff is the responsibility of the Ministry of Health and Consumer Affairs. CSN, following recommendations of the EC, has set up a national radiation monitoring programme that surveys air, coastal and river waters, soil, some food stuffs and drinking water, this being supplementary to the nationwide programme. Reporting of discharges and environmental data to the European Commission is performed regularly pursuant to articles 35 – 37 of the Euratom Treaty. The infrastructure for environmental monitoring has been verified by the European Commission three times, in accordance with Article 35 of the Euratom Treaty, most recently at the Cofrentes NPP, without major observations.

Of relevance for environmental surveillance is also the network for radiation monitoring in air operated by the CSN, which currently comprises 25 stations nationwide. Outside the direct influence by the CSN, but relevant to the national infrastructure, is the network of more than 900 monitoring stations for gamma dose rate, administered by the Ministry of Internal Affairs.

No specific action is taken by the CSN in the area of assessment of radiation effects in the environment *per se,* outside the effects on human health. It can be noted, however, that the CIEMAT has been highly active in European research projects in this area during recent years.

The discharge limitation and environmental monitoring programmes are adequate for the purpose, regularly evaluated and updated, carefully executed and governed by clear instructions. The review has in this area been constrained by time to focus on NPPs, but some observations made in other areas corroborate this view. It can be concluded that an infrastructure is in place for adequate 106 limitation, monitoring and evaluation of environmental radioactivity caused by the operation of NPPs,

and that CSN plays a clear role in this area. In future authorisation of major facilities causing discharges, CSN might wish to include also consideration of environmental effects per se in its assessment scheme.

8.7. Natural radiation

8.7.1. General aspects

Following the provisions laid out in Royal Decree 738/2001 substantial activity has in recent years gone into the characterisation of sources, and pathways of exposure, to natural radiation. Partly, this stems from the EU BSS, in which member states are requested to identify those activities that might give rise to such levels of radiation that health protection may be a concern. Since this now a concern for CSN, a special policy discussion on this matter was organised during the IRRS mission. The discussion clearly revealed the commonality between nations with regard to the nature of the problem, and with regard to ways to solve, or at least reduce, such problems. The outcomes of a number of specific projects were discussed, as well as the relative efficiency of different approaches to regulation and risk reduction. It was pointed out that a number of international guidelines, e.g. developed by the IAEA, are available in this area.

CSN has surveyed a variety of environments and activities in which health concern may arise. This also includes mapping of radiation in the territory of Spain, the MARNA Project. Out of a substantial list of surveyed environments/activities, a few emerge as requiring additional attention, *inter alia* the ceramic industry, fertilizer industry, use of thorium in welding, and carbon combustion. The relevant authority, if the activity is on the list, should request impact assessments to be transmitted to the CSN, for review. The conclusion by the CSN is subsequently handed over to the Competent Authority with a recommendation. In cases of substantial risk, however, the CSN is authorized to intervene and its decisions become mandatory. The somewhat complex infrastructure in this matter has, by CSN, been proposed to be clarified through relevant changes to the Royal Decree on health protection.

The identification and, when necessary, control of activities and environments that may give rise to health concerns have been given increased attention recently, and can be considered adequate for the purpose.

9. Management system

9.1. Introduction

The IAEA Safety Requirements publication GS-R-3, issued 2006, defines the requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements. This integration aims to ensure that safety is properly taken into account in all the activities of an organisation in order to ensure the protection of people and the environment. The requirements are applicable on management systems for industrial nuclear facilities and activities as well as for regulation of such facilities and activities. GS-R-3 with its integrative approach, emphasis on safety culture promotion and strong focus on continuous improvement can be seen as an evolution of the earlier concept of quality management.

Background

In 1996 CSN decided to implement a quality management system based on the ISO 9004-2 standard. This system was updated in 2002 with some elements from the ISO 9001-2000 standard and the EFQM (European Foundation of Quality Management) excellence model and an activity planning system was developed. Two EFQM self assessments were performed.

After the publishing of GS-R-3 in 2006, CSN decided to bring their existing quality system in line with the new IAEA Requirements. As a basis for this work, and as a part of the IRRS self-assessment, a correlation table was developed between the requirements of GS-R-3, ISO 9001-2000 and the existing CSN quality system. Several elements were identified that needed to be developed in order to meet GS-R-3. As a result of the work so far a new management system manual has been developed which closely follows the structure of GS-R-3. As an important part of this work a new process map has also been created. Some of the management procedures as well as a number of administrative and technical procedures have been updated. A handful of new management procedures have been developed. The new management system manual was approved by the CSN Council on 9 January 2008 and signed by the President 21 January 2008. Most of the elements required by GS-R-3 are in place. Remaining parts are identified and the complete implementation is foreseen within the next three years.

Well developed elements of the CSN management system

Coverage and documentation

The documentation structure is well defined and on the whole well developed. Management system documentation is ordered in a hierarchy from the system manual at the top, over the organisation manual, management procedures, administrative and technical procedures and records. The whole structure contains about 150 documents; the largest group is technical procedures with about 90 documents. As a result the technical functions of CSN are especially well covered by the documentation. The system clearly reflects the graded approach where more attention and resources are given to the regulation of those facilities and activities that are most complicated and pose the highest risk. For the regulation of radiation facilities types 3 and 4, some regional authorities conduct these activities on agreements with CSN, however CSN issues the requirements and train the inspectors in these cases.

The process map includes 19 processes needed to achieve the objectives of CSN, to provide the means to meet all requirements and to obtain the products of the organisation.

The processes are divided into the following categories:

- Strategic processes; functions of the Council, internal and external communication, and development of regulations (currently 3 processes and 11 management procedures).
- Operational processes; regulation of nuclear and fuel cycle facilities, regulation of radiation facilities, regulation of transports, regulation of radiological services, licensing of NPP and radiological staff, regulation of radiation protection and environmental monitoring, emergency preparedness and physical protection (currently 7 processes and 16 management procedures).
- Support processes; institutional relations, international relations, economy and financing, research and development, documentation, legal issues, human resources, information system and administration of the management system (currently 9 processes and 9 management procedures).

The operational processes are described on standardised sheets in the management system manual. These descriptions include objectives, limits, process owner, inputs to the process, outputs, receivers of outputs, performance indicators (for the main processes), information system data, labels and references of associated procedures.

All management system documents are available on the intranet.

Management commitment, planning and responsibilities

Responsibilities and authorities for all activities are defined within the management system as well as the decision making process. The Council is ultimately responsible through the President for the management system. The Subdirector for Planning, Information Systems and Quality is responsible for co-ordinating the development and implementation of the management system.

Organisational values have been defined in a specific multi-step project involving a large number of the staff. The finally established values are independence, transparency, competence and responsibility, and commitment.

Management procedures exist and are implemented for follow up of the strategic and annual planning and of the performance indicators. The basic document is a five year strategic plan (currently 2005-2010). This plan contains the mission and vision of the CSN, an analysis of the social environment, strategic results to be obtained, strategies and objectives, and activities in different areas. The plan is printed in an attractive format for stakeholders and is reviewed every year. The strategic plan provides the basis for annual targets which are elaborated in an annual working plan during the fourth quarter of the year. Every quarter a management follow up is made of the annual working plan as well as of the direct performance indicators (score card) addressing for instance performed versus planned inspections, hours devoted to inspections, reported versus planned applications, applications reported on time, pending applications exceeding deadlines, and average activation time of all the members of the standby teams during emergency drills. The Secretary General compiles the quarterly reports from the Directorates and other units and submits the results to the Council.

Every week the Directorates make a follow up of regulatory activities, setting priorities and allocating resources. This is done by management committees including directors, subdirectors and ad hoc invited staff. A list of actions for these follow ups is derived from the documentation system.

Resource planning is done within the Directorates so each unit (technical area) knows how many working hours that can be spent on defined projects. Individual planning is done on that basis by the unit head in communication with the staff. Reserve time is kept for unforeseen events.

General competence requirements to enter the CSN are defined. Permanent staff has to take a comprehensive technical, legal and English language test to become "Civil Servants". An internal training programme exists with mandatory courses for inspectors and the emergency preparedness staff.

Management of information and knowledge of CSN as a resource

Information and knowledge management such as making necessary technical information available and develop the knowledge base through R&D-projects are covered by management procedures.

CSN has a well developed IT-based information management system on the intranet for licensing purposes, registration purposes, inspection reports, equipment and source inventories, etc. The system holds all relevant records in digital format, several associated databases provide reference information, such as safety assessments and operational documentation from the facilities. This user friendly system is used by the CSN as well as to applicable extent by its associated regional authorities.

The document management system supports consistent and timely regulatory decision-making by providing staff with prompt access on the intranet to previous regulatory decisions and the technical assessments underpinning them, enabling rapid comparison of information submitted by operators with previous CSN reviews, assessments and decisions.

Control of documents and records

In principle all documents are handled by the electronic documentation system which makes all documents available (with some justified exceptions) to all staff. All documents are well controlled. Incoming documents are allocated directly to the responsible officer who makes a first review and if needed sets a response time. Licensing activities are put on a data file that automatically provides monitoring of deadlines. All records of the Council are available on the intranet.

External communication

In line with the organisational value of transparency CSN has an extremely proactive information policy. All decisions, inspection reports and other matters of interest for stakeholders are immediately after signing posted on the website if not protected for individual integrity or security reasons.

Opportunities for improvement of the CSN management system

It should be pointed out that CSN has done a good job in its IRRS self-assessment to identify areas and items where more work is needed to bring the management system in line with GS-R-3. The mission has checked these items and also identified a few specific additional points mostly with regard to assessment and improvement of the management system.

Documentation of the management system

The strategic and supportive process descriptions have been developed but are not yet formally issued. Updating priority has rightly been given to the operational processes. The organisational policy statement in the management system is more dealing with strategies than policy. A more concise policy statement from the Council to stakeholders about what they can expect the CSN to deliver remains to be developed.

The process map is displayed on the intranet as a document. The current practice in some other regulatory bodies is to use a software application that allows management system documents to be opened directly from the process map. This makes it easier to navigate in the system and to see how the different parts tie together.

Promotion and support of a strong safety culture

For a regulatory body it might be more appropriate to talk about a regulatory culture than a safety culture. How to apply the concept of safety culture on a regulatory body is elaborated to some extent in INSAG-4 and INSAG-15. Currently there is no mechanism in place at CSN to promote or assess the regulatory (safety) culture. However, a decision has been taken to perform periodic working climate surveys starting 2009 at the latest. These could be developed to cover the regulatory (safety) culture aspects.

Consideration of stakeholders expectations

CSN has many interfaces with institutional parties as well as international organisations, industry stakeholders, environmental organisations and the interested public. Several procedures in the management system explain how to interact with these parties but there is no description in the management system and criteria how to investigate stakeholders expectations and follow up on the results.

Human resources

Until now there has been no systematic approach to internal training at CSN based on organisational needs. However, a decision has recently been taken to implement the systematic approach to staffing and training as mentioned in chapter 3. The new system will provide management with a much better tool for assessing the organisational competence and follow up of individual staff competence. The competence profiles to be developed for each technical area will also provide good tools for well advanced planning of knowledge transfer in connection with retirements.

Management of organisational change

CSN is a stable organisation with few changes. However, needs have been identified to adjust the organisation of some technical areas to better cope with the actual work load. There are also ideas to move some functions from the President's technical cabinet to the line organisation. Currently there is no procedure in place to manage and assess organisational changes. An administrative procedure is foreseen but no decision has been made yet.

Management self-assessment

As mentioned management procedures exist and are implemented for follow up of the strategic and annual planning and of the performance indicators. However, currently there is no evaluation of the improvement of the regulatory (safety) culture in the management self-assessment concept as required by GS-R-3.

Independent assessments on behalf of senior management

Currently there is no internal audit programme in place. An audit procedure from 1999 exist and a draft update to reflect the language of GS-R-3. Between 1996 and 2006 seven internal audits of the CSN quality system were performed by two auditors (one now retired). GS-R-3 is quite clear about independent assessments to be conducted regularly on behalf of senior management. An organisational unit, or an individual, provided with the necessary authority, shall be assigned the responsibility to manage these assessments. The practice in many regulatory bodies is to select and train a group of auditors from different departments and to compose audit teams from this staffing pool, depending on the work to be audited. Auditors shall not assess their own work. A common practice is also to develop an audit programme to ensure that all management system processes are audited within a certain time period, often 3-4 years depending on the scope of activities.

Management system review

CSN has done some ad hoc reviews of parts of the management system, such as the earlier mentioned EFQM self-assessments. A review of the main system elements was also made by consultants in November 2007 and recommendations were provided. However, there is no methodology and programme in place to conduct an overall management system review at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives of the organisation to be accomplished. A methodology needs to be developed for the conduct of the management system review and a mechanism established for handling of the results. For CSN, with a relatively large number of internal procedures in the management system, it seems well motivated to carry out these reviews to make sure that the management system provides consistency as well as the necessary flexibility in the regulatory activities.

Systematic approach for handling of non-conformances and potential non-conformances

A system of Council orders exists for correction of more high level matters, but there is no procedure and programme in place to handle non-conformances with regard to management processes and products of the CSN. This is a matter also connected with an internal audit programme. Regarding potential non-conformances, there has been a lot of exchange between CSN and other regulatory bodies abroad to exchange views on regulatory and management matters in order to identify potential non-conformances and opportunities for improvement. Also the regular meetings in INRA, WENRA and the Ibero American Forum well as the IRRS mission are instruments for this. However, no regular feedback programme from other organisations is defined within the management system.

Identification and monitoring of improvement actions

There is no general procedure or mechanism in place to identify opportunities for improvement of the management system as well as to monitor improvement actions and check the effectiveness of the improvements. Such a mechanism could be built into each process and be managed by the process owners. To solicit comments and suggestions related to IT-problems, the CSN statute and the SISC programme, mailboxes have been established on the intranet for comments and suggestions from the staff. This could serve as a model for commenting on the functioning of all management processes.

Recommendations, suggestions and good practices

(1) **BASIS**: GS-R-3 §6.3 states that "*Independent assessments shall be conducted regularly on behalf of senior management:*
– To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;…"

(2) **BASIS**: GS-R-3 §6.4 states that *"An organisational unit shall be established with the responsibility to conduct the independent assessments…"*

(3) **BASIS**: GS-R-3 §6.5 states that *"Individuals conducting independent assessments shall not assess their own work …"*

(4) **BASIS**: GS-R-3 §6.6 states that *"Senior management shall evaluate the results of the independent assessment, take necessary actions, record and communicate their decisions…"*

(5) **BASIS**: GS-R-3 §6.11 states that *"The causes of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence."*

(6) **BASIS**: GS-R-3 §6.12 states that *"Products and processes that do not conform shall be identified, segregated, controlled, recorded and reported …and evaluated…".*

(7) **BASIS**: GS-R-3 §6.13 states that *"Concessions granted to allow acceptance of a non-conforming product or process shall be subject to authorization…"*

(8) **BASIS**: GS-R-3 §6.14 states that *"Corrective actions for eliminating non-conformances shall be determined and implemented…"*

R4 **Recommendation**: CSN should formalise and implement an internal audit programme of the management processes. The programme should ensure that all processes are audited within a defined time period. To support this programme a number of internal auditors should be selected among the staff and given adequate training. In connection with the audit programme, a systematic approach to the management of non-conformances of processes and products should be developed and formalised.

(1) **BASIS**: GS-R-3 §6.7 states that *"A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished."*

R5 **Recommendation**: CSN should develop a methodology and implement management system reviews to be conducted at planned intervals by internal or/and external resources. This programme should ensure the continuing suitability and effectiveness of the management system as a whole and its ability to enable the objectives of the organisation to be accomplished.

(1) **BASIS**: GS-R-3 §3.7 states that *"Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization."*

(2) **BASIS**: GS-R-3 §2.8 states that *"the policy statement shall be included in the management system documentation.."*

S22 **Suggestion**: CSN should insert into the management system manual a more concise organizational policy statement which gives a clear message from the Council to stakeholders about what they can expect the CSN to deliver.

(1) **BASIS**: GS-R-3 §2.5 states that *"The management system shall be used to promote and support a strong safety culture..."*

§6.2 states that Senior management and management at all levels in the organisation shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture…

Recommendations, suggestions and good practices

S23 **Suggestion**: To support management self-assessments, CSN should perform assessments (surveys) of the regulatory (safety) culture among all staff at planned intervals and develop a mechanism to feedback and act on the results. These surveys could be included in the planned working climate surveys.

(1) **BASIS**: GS-R-3 §2.9 states that *"Documents..of the management system... shall be readable, readily identifiable and available at the point of use."*

S24 **Suggestion**: CSN should implement an up to date software application on the intranet of the process map and make it possible to open all attached documents from the map.

(1) **BASIS**: GS-R-3 §6.17 states that *"Opportunities for the improvement of the management system shall be identified and actions to improve the processes shall be selected, planned and recorded."*

(2) **BASIS**: GS-R-3 §6.17 states that *"... Actions for improvement shall be monitored through to their completion and the effectiveness of the improvement shall be checked."*

S25 **Suggestion**: CSN should implement a mechanism to identify opportunities for improvement of the management system as well as to monitor improvement actions and check the effectiveness of the improvements. An instrument for this could be mailboxes on the intranet, attached to each management system process, for collecting comments and suggestions from the staff.

(1) **BASIS**: GS-R-3 §5.28 states that *"Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified."*

§5.29 *states that "The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised."*

S26 **Suggestion**: CSN should develop a procedure to manage and assess its organisational change.

(1) **BASIS**: GS-R-3 §2.9 states that *"Documents ... of the management system... shall be readable, readily identifiable and available at the point of use."*

G16 **Good practice**: CSN has a well developed documentation and information management system on the intranet that supports a consistent and efficient regulatory decision-making by providing staff with prompt access to all necessary documents as well as reference information such as previous regulatory decisions and safety assessments. The system also holds design and operational documentation from the regulated facilities.

10. Physical protection in nuclear installations

As a part of this IRRS Mission, at the invitation of CSN, a team reviewed the legal and regulatory aspects of nuclear security for nuclear and radioactive material in use, storage and transport as it relates solely to the roles and responsibilities of CSN. As part of its efforts the team observed a joint physical protection inspection conducted by CSN, the national police (CPN) and the Guardia Civil (GC.). The team also interviewed representatives of the Ministry of Interior and Ministry of Industry, Tourism and Trade to assess the interface and coordination between CSN and these organizations. The results of the team's assessment were provided independently of this report due to the confidential nature of much of its content. However, some elements of this report have been included herein at the discretion of CSN.

Appendix

I. List of participants

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18. William **Dean**	United States Nuclear Regulatory Commission	WMD@nrc.gov
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II. Mission programme

	Mission programme	
	Sunday, 27 January 2008	
14: 00 – 18:00	Opening Team Meeting	
	Monday, 29 January 2008	
09:00 – 18:00	Welcome and Introduction	C. Martínez Ten
	Opening remarks	U. Schmocker
	Introduction of IRRS Review Team	All Team members
	Briefing for IRRS Team	J. Barceló
	Introductions and working arrangements	I. Mellado
		JC Lentijo
	Detailed presentations on each of the areas to be covered by the review	CSN counterparts
	Closing remarks	U. Schmocker
17:00 – 18:00	Daily IRRS Review Team Meeting	All Team members
	Drafting of Report	
	Tuesday, 29 January 2008	
08:30 – 16:00	Group interactions	IRRS Team
16:00 – 17:00	Policy issue discussion	IRRS Team
17:00 -	Daily IRRS Review Team Meeting	IRRS Team
...	Drafting of Report	
	Wednesday, 30 January 2008	
08:30 – 16:00	Group interactions	IRRS Team
16:00 – 17:00	Policy issue discussion	IRRS Team
17:00 -	Daily IRRS Review Team Meeting	IRRS Team
...	Drafting of Report	
	Thursday, 31 January 2008	
Site Visits	Interview Mityc + ENRESA + CSN. Policy on waste management	Larsson
		Osojnik
	Inspection environmental radiological surveillance,	Larsson
	Saelices (Ciudad Rodrigo)	Osojnik
	Interview MITYC	Schmocker
		Loy
		Reyes
		Jende
	Inspection Medical Facility Radiotherapy + X rays,	Krembel
	Ramón y Cajal Hospital	Carvalho Soares

Mission programme

Thursday, 31 January 2008

Site Visits	Plant Inspection Physical Protection Cofrentes NPP (Valencia)	Price Dean Gregoric
	Plant Inspection Heating exchangers and UHS at Sta. María de Garoña NPP (Burgos)	Biro Jarvinen
08:30 – 16:00	Group interactions	IRRS Team
16:00 – 17:00	Policy issue discussion	IRRS Team
17:00 -	Daily IRRS Review Team Meeting	IRRS Team
...	Drafting of Report	

Friday, 1 February 2008

Site Visits	Inspection Medical Facility: Nuclear Medicine, Ramón y Canal Hospital	Krembel Carvalho Soares
	Inspection External Dosimetry Laboratory: CIEMAT	Olerud
08:30 – 16:00	Group interctions	IRRS Team
16:00 – 17:00	Policy issue discussion	IRRS Team
17:00 -	Daily IRRS Review Team Meeting	IRRS Team
...	Drafting of Report	

Saturday, 2 February 2008

17:00 -	Daily IRRS Review Team Meeting	IRRS Team

Sunday, 3 February 2008

Site Visits	Inspection El Cabril LIRW Repository (Córdoba)	Osojnik
	Plant Inspection Nuclear Facility, Plant Operations Juzbado Fuel Fabrication (Salamanca)	Biro Jarvinen
...	Drafting of Report	

Monday, 4 February 2008

Site Vistis	Plant Inspection control of radioactive effluents at Trillo NPP (Guadalajara)	Larsson
09:00 – 12:00	Interview CIEMAT	Schmocker Loy Reyes Jende
09:00 – 16:00	Inspection Industrial Gammagraphy SCI (Madrid)	Duffy Markarovska Carvalho Soares
08:30 – 17:00	Group interactions	IRRS Team
17:00 -	Daily IRRS Review Team Meetiing	IRRS Team
...	Drafting of Report	

Mission programme		
Tuesday, 5 February 2008		
08:30 – 09:00	Inspection Industrial Accelerators (Ionmed – Cuenca)	Duffy Markarovska
08:30 – 17:00	Group interactions	IRRS Team
17:00 -	Daily IRRS Review Team Meeting	IRRS Team
...	Drafting of Report	
Wednesday, 6 February 2008		
08:30 – 17:00	Group interactions	IRRS Team
17:00 -	Daily IRRS Review Team Meeting	IRRS Team
...	Report Handover to Counterpart	
Thursday, 7 February 2008		
	Plenary	IRRS Team CSN Counterpart
Friday, 8 Feruary 2008		
Exit Meeting		

III. Site visits

Name	Type	Ubication
1. MITYC and ENRESA	Policy on waste management	*Madrid*
2. Dosimetry Laboratories - CIEMAT	External and Internal Dosimetry Labratory	*Madrid*
3. Ramón y Cajal Hospital	Medical Facility RT, NM, X-ray	*Madrid*
4. Sta. Mª de Garoña Nuclear Power Plant	Plant inspection, heating exchangers and UHS	*Burgos*
5. Cofrentes Nuclear Power Plant	Plant Inspection, Physical Protection	*Valencia*
6. Saelices	Inspection environmental radiological surveillance	*Ciudad Rodrigo*
7. CIEMAT	Interview	*Madrid*
8. SCI	Inspection Industrial Radiography	*Madrid*
9. Juzbado Fuel Fabrication	Plant Inspection Nuclear Safety, Plant Operations	*Salamanca*
10. Trillo Nuclear Power Plant	Plant Inspection Control of radioactive effluents	*Guadalajara*
11. El Cabril LIRW Repository	*Inspection*	*Córdoba*
12. IONMED	Inspection Industrial Accelerator	*Cuenca*

Item	Subject Area	IRRS Experts	Lead Counterparts	Support
I	Responsibilities legislative and governmental	U. Schmocker J. Loy L. Reyes E. Jende C. Price	I. Mellado J. Lentijo Torres J. Zarzuela Rodríguez	Méndez Pelayo Sanz
II	Responsibilities and Functions of the regulatory body	U. Schmocker J. Loy L. Reyes E. Jende C. Price	I. Mellado J. Lentijo Torres J. Zarzuela Rodríguez	Méndez Pelayo Sanz
III	Organization of the regulatory body	U. Schmocker J. Loy L. Reyes E. Jende C. Price	I. Mellado J. Lentijo Torres J. Zarzuela Rodríguez	Méndez Pelayo Sanz
IV	Authorization	M. Herttrich A. Hall L. Biro M.-L. Jarvinen S. Matsuura H. Olerud D. Krembel J. Duffy O. Makarovska C. M. Larsson I. Osojnic	J. Zarzuela Vázquez A. Munuera De la Vega J. Gil Rodríguez Álvarez Amor	López Ruiz Revilla
V	Review and assessment	M. Herttrich A. Hall L. Biro M.-L. Jarvinen S. Matsuura H. Olerud D. Krembel J. Duffy O. Makarovska	J. Zarzuela Vázquez A. Munuera De la Vega Rodríguez Álvarez Amor	López Ruiz Revilla
VI	Inspection and enforcement	M. Herttrich A. Hall L. Biro M.-L. Jarvinen S. Matsuura H. Olerud D. Krembel J. Duffy O. Makarovska C.-M. Larsson I. Osojnik	J. Zarzuela Vázquez A. Munuera De la Vega Rodríguez Álvarez Amor J. Gil C. Gil Ramos Cid Zamora	López Ruiz Revilla

Item	Subject Area	IRRS Experts	Lead Counterparts	Support
VII	Regulations and guides	M. Herttrich	Recarte	López
		A. Hall	Muñoz	Ruiz
		L. Biro	Ropero	Revilla
		M.-L. Jarvinen		Vázquez
		S. Matsuura		De la Vega
		H. Olerud		A. Munuera
		D. Krembel		Isasia
		J. Duffy		Robledo
		O. Makarovska		
VIII	Management System for Regulatory Body	U. Schmocker	I. Mellado	Méndez
		J. Loy	J. Lentijo	Pelayo
		L. Reyes	Torres	Sanz
		E. Jende	J. Zarzuela	
		C. Price	Rodríguez	
			Cepas	
X	Emergency Preparedness	Janko	E. Gil	
	Physical Protection	C. Price	Lardiez	
		W. Dean		
		M. Gregoric		

IV. Recommendations/suggestions/good practices from the IRRS mission

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
1	Legislative and governmental Responsibilities	S1	Suggestion: The CSN should consider, in line with the practice adopted in other countries, whether to propose a change in the Law on Fees and Public Prices that would apply a base annual fee and charges for regulatory activities generated by licence holders so as to establish a 'price signal' for operators.
		G1	Good practice: The detailed statement of operator responsibility now established in the Nuclear Energy Law by the 2007 amendments.
		S2	Suggestion: In implementing the new legal provisions for the operation of the advisory committee on transparency and communications, the potential for there to be unintended adverse impacts of transparency and communications on safety should be carefully considered by CSN and debated with the advisory committee.

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
2	**Responsibilities and functions of the regulatory body**	*No recommendations, suggestions or good practice identified*	
3	**Organization of the Regulatory body**	S3	Suggestion: CSN should consider an approach that will facilitate the recruitment of staff at above the base-level for technical staff and non technical professionals.
		S5	Suggestion: The plans to enhance the organizational expertise in risk assessment, operating experience and human organization factors should be implemented with high priority. Other resource skill allocations should consider new facilities being proposed as well as the new demands in security, communications, international relations and compliance with law 33/2007 regarding radiation protection of patients.
		S6	Suggestion: The training of CSN inspectors should consider the addition of soft skills training such as communications, report writing and conflict resolution.
		S7	Suggestion: CSN should use its authority to establish a technical advisory committee.
4	**Activities of the regulatory body**		
	Authorization	*No recommendations, suggestions or good practice identified*	
	Review and assessment	G2	Good practice: CSN has developed and implemented a user-friendly PSA tool for use by staff not expert in the understanding of psas. This contains detailed plant data for each of Spain's npps and supports the SISC system and its Significance Determination Process. This PSA tool enables all CSN technical staff, and not simply those who are experts in PSA, to understand the plant systems and operational conditions important to safety. In addition a special PSA tool is available on the CSN intranet for use by all inspectors The tool facilitates the risk-informed selection of the SSC for the SISC inspection.
		G3	Good practice: Regular meetings with Spanish radiation protection societies and the Spanish health physics society are also organized to discuss review and assessment issues.
	Development of regulations	S8	Suggestion: The planned CSN policy and overall strategy for the development of binding regulations and guides should be developed in the near future. It should respond to needs identified and experience made with the current activities to further enhance consistency and completeness of the Spanish 'regulatory pyramid'. The approach should ensure that the requirements imposed by the

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
4	**Activities of the regulatory body**		
	Development of regulations	S9	Suggestion: CSN should compile a uniform glossary to be used for all legally based regulatory documents. This glossary should also enable and support the proper understanding or interpretation of the respective language used in the countries of origin, as well as in IAEA standards.
		G4	Good practice: CSN practices a well based and thorough approach that requires the licensees to systematically assess advances in international standards and to take relevant standards into account and to make them binding for licensees. The practice of annual reviews of the development of safety standards related to the licensing base as well as considering additional standards and practices in the context of license renewal processes supports continuous development of plant safety.
		S10	Suggestion: Regarding major backfittings, the state of the art of backfitting technology for comparable designs in other countries – not only the countries of origin – should be taken into account for more detailed conditions and requirements to the licensees.
		G5	Good practice: The CSN approach to keep track of the development of regulations and guides in countries of origin to take into consideration comments from interested parties and the feedback of experience is very systematic and comprehensive.
		S11	Suggestion: CSN should address possible inconsistencies for Spanish regulations resulting from requirements from foreign sources as the countries of origin of design or the IAEA more directly. The experience made with the integration of different sources into the Spanish system of regulations and guides should be reported back for consideration by the respective institutions to promote resolution of such inconsistencies.
		G6	Good practice: The material available on the CSN web site, including guides and training courses in radiation protection, is comprehensive for the various practices and is an efficient tool to contribute to safety improvements among the many operators involved in radiation facilities or using X rays for medical diagnostic purposes.

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
4	**Activities of the regulatory body**		
	Inspection and enforcement	G7	Good practices: CSN management of the inspections with all the documents available on the intranet across all facilities and activities is highly effective. The processes include the regular review of inspections and their findings as well as the follow up of plans with associated resources. The conduct of the inspection programmes in this area as well as others covered by the IRRS review is made in a transparent and traceable way.
		G8	Good practice: The SIC'S programme results are thoroughly presented on the CSN web site. The status of the utility is clearly presented and the related safety questions if any are presented in an easily understandable way. Also in-depth information can be found.
		S12	Suggestion: CSN should evaluate the effectiveness of the new SIC'S inspection programme together with the other inspection, review and assessment activities with respect to the coverage of the issues and activities important to safety.
		S13	Suggestion: CSN should consider the balance of the resources allocated to the human and organizational issues as well as the number of inspections in which these issues are addressed. In planning inspections of human and organizational factors, CSN should also consider what is an appropriate level and way of addressing management and policy issues of the licensees.
		R1	Recommendations: CSN should implement a systematic way of compiling and presenting the results obtained, the trends and consequences drawn from inspections and review and assessment for all nuclear installations where applicable, and should give feedback to the licensee. This should be undertaken on a periodic basis.
		S14	Suggestion: As inspection reports of the nuclear power plants and fuel fabrication facilty as well as the SIC'S information package are being put onto the CSN web site, CSN should have a standard format for presenting the scope of the inspections and the findings together with its evaluation of the safety significance and the information of the nuclear power plant should be in one place. CSN should also assess the benefit of presenting inspection reports with utility comments and their resolution at the web site.

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
4	**Activities of the regulatory body**		
	Inspection and enforcement	G9	Good practice: Inspection reports for radiation facilities and X ray facilities for medical diagnosis are published on the CSN web-site. The only information that is excluded is information that is considered sensitive (personal data, commercial, security aspects etc). This makes the CSN activity transparent to the public, raises public credibility in the regulatory system and can promote the safety of the facilities.
		R2	Recommendation: From all its inspections in x-ray diagnostic and radiation facilities, CSN should build and express an opinion about the results obtained, the trends and consequences drawn in the different practices using radioactive sources, and to give feedback to the licensee. This should be undertaken in a periodic way.
		S15	Suggestion: CSN should consider to upgrade their internal procedures to a formal procedure for inspection of Dosimetry Services.
		G10	Good practice: The CSN inspection programme for facilities for operational waste disposal and for discharge control, and the verification of the protection of the public and the environment from operating and decommissioned facilities through environmental monitoring, is highly structured, conducted in a highly competent manner, and followed up according to clear procedures.
5	**Safety and security of radioactive sources**	S16	Suggestion: CSN should establish a formal mechanism for exchange of information with the Customs about notification that a radioactive source has actually entered or left the country to make it fully traceable.
		G11	Recommendations, Suggestions or Good Practices Good practice: Spain has established strong measures for ensuring effective management of sources at the end of their life; a condition of license that there be arrangements for return to the supplier or for proper disposal or storage, supported by financial guarantees. In exceptional circumstances confiscation of the source and its recovery from public fund is provided.
		G12	Good practice: Spain has a consistent and stable policy of organizing and carrying out state campaigns for restoring appropriate control over orphan sources. IAEA methodology for combined administrative and physical search of orphan sources is comprehensively implemented.

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
6	**Transport of radioactive material**	S17	Suggestion: To support the work of the Committee for the Coordination of the transport of dangerous goods of the Ministry of Public Works, Memoranda of Understanding or equivalent should be established where possible, with the other competent authorities with competences in the inspection of dangerous goods.
		G13	Good Practice: The Transport Management Database System incorporating databases on packages subject to approval, packages not subject to approval, carriers, Type B(U) packages, authorizations, inspections, and incidents and all other relevant documentation is considered to be comprehensive, user friendly and a practical management tool.
		G14	Good Practice: To assist all relevant stakeholders the CSN has for a number of years produced a detailed correlation table between the current IAEA TS-R-1 and the current ADR by theme, paragraph number and a comment indicating the relevant changes in each document. This pro-active approach is very practical and meets the needs of the operators, staff, etc.
7	**Emergency preparedness**	S18	Suggestion: CSN should upgrade guidance on radiological emergencies to support use of the IAEA threat assessment categories.
		S19	Suggestion: CSN should continue developing planning for the actions to be taken after an emergency., taking into account the specific national conditions and international recommendations.
		S20	Suggestion: CSN should consider extending the existing national guidance for emergency (group one) workers by introducing a more selective specification of conditions based on IAEA EPR-method-2003.
		G15	Good practice: CSN established an integrated network-based database system for management, control and recording of doses, enabling control of doses received by emergency worker. Effective management of dose records significantly contributes to an effective emergency management and protection of emergency workers.

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
7	**Emergency preparedness**	G16	Good practice: An effective framework for managing the situation in case of uncontrolled source emergencies in metallurgy recycling sector has been established. Adaptation of the Protocol for Radiological Surveillance of Metal Recycling, a Collaboration of Government and Industry, with effective involvement of CSN, ensures a high level of readiness for this type of emergency at national level.
8	**Infrastructure for radwaste, decommissioning and remediation and environmental surveillance**	G17	Good practice: The national system involves the obligation of ENRESA to draw up the General Waste Management Plan (PGRR), which cover all waste streams and also incorporates the views of different affected parties in the establishment of the national strategies. The PGRR is a comprehensive document that allows for assessment of interdependencies and priorities.
		S21	Suggestion: CSN should work towards, and the Government should consider, adjusting the procedure for approval of the General Radioactive Waste Plan, or PGRR, so that the plan is submitted to the Ministry of Industry, Tourism and Commerce (MITYC), together with a technical review of the safety- and radiation protection- related matters of the same document by the CSN, to assist the Ministry in judging the technical considerations underpinning the strategy laid out in the PGRR.
		S22	Suggestion: The CSN should work with the Competent Authorities to regulate the establishment and maintenance of a national centralised inventory of existing and anticipated radwaste, including also waste that could be generated outside regulated facilities.
		R3	Recommendation: CSN should work with other competent authorities to encourage the development and communication of plans for final disposal of spent fuel and HLW, and contribute to setting the appropriate targets and conditions that would, from all points of view, govern the process, so that there is no unnecessary delay in the solution of the problem, and that also gradually would improve the estimates of future costs for the final radwaste management.
		G18	Good practice: In the area of decommissioning of nuclear power plants and other fuel cycle facilities, an infrastructure has developed and matured over the years, including regulatory experience, that allow decommissioning projects to be carried out efficiently and with minimal delays. This may serve as an international benchmark.

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
9	**Management system**	R4	Recommendation: CSN should formalise and implement an internal audit programme of the management processes. The programme should ensure that all processes are audited within a defined time period. To support this programme a number of internal auditors should be selected among the staff and given adequate training. In connection with the audit programme, a systematic approach to the management of non-conformances of processes and products should be developed and formalised.
		R5	Recommendation: CSN should develop a methodology and implement management system reviews to be conducted at planned intervals by internal or/and external resources. This programme should ensure the continuing suitability and effectiveness of the management system as a whole and its ability to enable the objectives of the organisation to be accomplished.
		S23	Suggestion: CSN should insert into the management system manual a more concise organizational policy statement which gives a clear message from the Council to stakeholders about what they can expect the CSN to deliver.
		S24	Suggestion: To support management self-assessments, CSN should perform assessments (surveys) of the regulatory (safety) culture among all staff at planned intervals and develop a mechanism to feedback and act on the results. These surveys could be included in the planned working climate surveys.
		S25	Suggestion: CSN should implement an up to date software application on the intranet of the process map and make it possible to open all attached documents from the map.
		S26	Suggestion: CSN should implement a mechanism to identify opportunities for improvement of the management system as well as to monitor improvement actions and check the effectiveness of the improvements. An instrument for this could be mailboxes on the intranet, attached to each management system process, for collecting comments and suggestions from the staff.
		S27	Suggestion: CSN should develop a procedure to manage and assess its organisational change.

	Areas	IAEA Comment No. R: recommendations S: suggestions G: good practices	Recommendations, suggestions or good practices
9	**Management system**	G19	Good practice: CSN has a well developed documentation and information management system on the intranet that supports a consistent and efficient regulatory decision-making by providing staff with prompt access to all necessary documents as well as reference information such as previous regulatory decisions and safety assessments. The system also holds design and operational documentation from the regulated facilities.
10	**Physical protection in nuclear installations**	As a part of this IRRS Mission, at the invitation of CSN, a team reviewed the legal and regulatory aspects of nuclear security for nuclear and radioactive material in use, storage and transport as it relates solely to the roles and responsibilities of CSN. As part of its efforts the team observed a Pjoint physical protection inspection conducted by CSN, the national police (CPN) and the Guardia Civil (GC). The team also interviewed representatives of the Ministry of Interior and Ministry of Industry, Tourism and Trade to assess the interface and coordination between CSN and these organismos.	

V. Reference material provided by CSN

[1]	**Preparatory meeting presentations**
	Authorization Nuclear & Radiation Facilities
	CSN Functions and Organization
	CSN management system
	CSN-Institutional-International Relations and Communication
	CSN-Organization
	Developments of guides and regulations IRRS
	Emergency Preparedness
	Inspection-Enforcement process
	IRRS Spain Pre-meeting Feb 2007
	IRRS-Self-Assessment
	Legal Framework
	Nuclear Security
	Radiation Protection Overview
	Regulatory-Control Radioactive Waste-Decommissioning
	Review and Assessment
	Transport

[2]	**Laws**
	Law Public Prices and Fees
	Law Creation CSN

[2] Laws

Law on Nuclear Energy

Law Rights of Access to Information

Law 15/1980, Creating the Nuclear Safety Council

Law 14/1999, on Fees and Public Prices for Services Rendered by Nuclear Safety Council

Law 33/2007 amendment on Creating the Nuclear Safety Councils (Law 15/1980)

Law 25/1964 on Nuclear Energy

Law 14/1999, of May 4th, on Fees and Public Prices for Services Rendered by the Nuclear Safety Council

[3] Resollutions

Royal Decree Basic Nuclear Emergency Plan

Royal Decree High-activity Sealed and Orphan Sources

Royal Decree Installation and use of X-Ray apparatus

Royal Decree Operational Protection outside workers

Resolutions of CSN

[4] Royal decrees

Royal Decree Regulation on Nuclear Risk Cover

Royal Decree Regulation on Nuclear and Radioactive Installations

Royal Decree Regulation on Sanitary Protection against Ionising Radiations

Royal Decree Statute of CSN

Royal Decree 1836/1999, of December 3rd, approving the Regulation on Nuclear and Radiation Facilities

Royal Decree 783/2001, of July 6th, approving the Regulation on Protection Against Ionizing Radiations

Royal Decree 387/1996, of March 1st, approving the Basic Directive on Risk in Transportation Hazardous Goods

Royal Decree 1546/2004, of June 25th, approving the Basic Nuclear Emergency Plan

Royal Decree (under approval) approving the Basic Directive on the planning of civil protection in presence of radiological risk

Royal Decree 407/1997

Royal Decree 393/2007

Royal Decree 1836/1999, of the 3rd of December, by approving the Regulation of Nuclear Installations and Radioactive (RINR)

Royal Decree 783/2001, of the 6th of June, approving the regulations on the protection of health against the Ionizing Radiation

Royal Decree 1891/1991, of the 30th of December, on the installation and use of X-ray devices Purpose Medical Diagnosis

[5] CSN Instructions

IS_01	IS_08
IS_02	IS_00
IS_03	IS_10
IS_04	IS_11
IS_05	IS_12
IS_06	IS_13
IS_07	

[6] Self-Assessment

IRRS self-assessment
Lessons learnt from Vandellos NPP-IMJ
Module List
Module I Legislative Govern Responsibilities
Module II annex Operating Permit NPP
Module II- Nuclear & Radiation facilities-JZJ
Module II –MRM
Module III Organization Chart 2 – MRM
Module III Organization Chart – MRM
Module IV - Nuclear facilities-TVM
Module IV - Radiation facilities-CAG
Module IV -Service entities –IAC
Module V - Nuclear facilities-AMB
Module V - Radiation facilities-CAG
Module V -Service entities –IAC
Module VI - Nuclear facilities-JGH
Module VII –MJM
Module VII – JACC
Public Expos-Waste-Decommissioning
Self Assessment Recommendations OSART-IMJ
Transport - FZM (1-15)(EGL-JLRG-MCRL-MTS)

[7] Other Referemce Material

CSN Strategic Plan 2005-2010
Emergency Response Organisation and
Indicators CSN-AHA
Management System Manual JACC
Policies GTP FFM Action Plan
Report to the Parliament 2005 summary
Report to the Parliament 2006 summary
Sixth General Radioactive Waste Plan
Management Procedure PG.IV.05, CSN Interventions in Disciplinary Proceedings as regards Nuclear Safety and Radiation Protection
Agreement of the Cabinet of Ministers, of October 1st 1999, relating to public information on the health protection measures applicable to and procedures to be adhered to in the event of a radiological emergency

[8] Joint Convention

Waste International Conference Report 1
Waste International Conference Report 2

[9] Nuclear Safety Convention

Convention on Nuclear Safety Report 1
Convention on Nuclear Safety Report 2
Convention on Nuclear Safety Report 3
Convention on Nuclear Safety Report 4

VI. IAEA Reference material used the review

[1] **IAEA Safety Standards Series GS-R-1** - *Legislative and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*

[2] **IAEA Safety Standards Series GS-G-1.1** - *Organization and Staffing of the Regulatory Body for Nuclear Facilities*

[3] **IAEA Safety Standards Series GS-G-1.2** - *Review and Assessment of Nuclear Facilities by the Regulatory Body*

[4] **IAEA Safety Standards Series GS-G-1.3** - *Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body*

[5] **IAEA Safety Standards Series GS-G-1.4** - *Documentation for use in Regulation of Nuclear Facilities*

[6] **IAEA Safety Standards Series GS-G-1.5** - *Regulatory Control of Radiation Sources*

[7] **IAEA Safety Standards Series GS-R-2** - *Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements*

[8] **IAEA Safety Standards Series GS-R-3** - *Management System for Facilities and Activities*

[9] **IAEA Safety Standards Series NS-R-1** - *Safety of Nuclear Power Plants: Design Safety Requirements*

[10] **IAEA Safety Standards Series NS-R-2** - *Safety of Nuclear Power Plants: Operation Safety Requirements*

[11] **IAEA Safety Standards Series NS-R-4** - *Safety of Research Reactors*

[12] **IAEA Safety Standards Series NS-G-4.1** - *Commissioning of Research Reactors*

[13] **IAEA Safety Standards Series SS115** - *International Basic Safety standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*

[14] **IAEA Safety Standards Series TS-R-1** - *Regulations for the Safe Transport of Radioactive Material*

[15] **IAEA Safety Standards Series WS-G-2.1** - *Decommissioning of Nuclear Power Plants and Research Reactors*

[16] **IAEA Safety Standards Series WS-G-2.2** - *Decommissioning of Medical, Industrial and Research Reactors*

[17] **IAEA Safety Standards Series WS-R-1** - *Near Surface Disposal of Radioactive Waste*

[18] **IAEA Safety Standards Series WS-R-2** - *Predisposal Management of Radioactive Waste including Decommissioning*

[19] **IAEA Safety Standards Series WS-G-2.3** - *Regulatory Control of Radioactive Discharges to the Environment*

[20] **IAEA Safety Standards Series WS-G-2.4** - *Decommission of Nuclear Fuel Cycle Facilities*

[21] **IAEA Safety Standards Series WS-G-2.5** - *Predisposal Management of Low and Intermediate Level Radioactive Waste*

[22] **IAEA Safety Standards Series WS-G-2.6** - *Predisposal Management of High Level Radioactive Waste*

[23] **IAEA Safety Standards Series WS-G-2.7** - *Management of Waste from the use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education*

[24] **IAEA Safety Standards Series WS-R-3** - *Remediation of areas contaminated by past activities and accidents*

[25] **IAEA Safety Standards Series WS-R-5** - *Decommissioning of facilities using Radioactive Material*

[26] **IAEA Safety Standards Series WS-G-6.1** - *Storage of Radioactive Waste*

[27] **IAEA Safety Standards Series RS-G-1.7** - *Application of the Concepts of Exclusion, Exemption and Clearance*

[28] **IAEA Safety Standards Series RS-G-1.8** - *Environmental and Source monitoring for Purpose of Radiation Protection*

[29] **IAEA Safety Standards Series RS-G-1.9** – *Categorization of Radioactive Sources*

[30] **IAEA Code of Conduct** *on the Safety and Security of Radioactive Sources*

[31] **IAEA Code of Conduct** *on the Safety of Research Reactors*

[32] **IAEA Guidance** *on the Import and Export of Radioactive Sources*

[33] **IAEA Safety Series No. 111-G-1.1** - *Classification of Radioactive Waste*

[34] **Safety Series No. 35 – G2** - *Safety in the Utilization and Modification of Research Reactors*

[35] **IAEA TECDOC 1388** - *Strengthening control over radioactive sources in authorized use and regaining control over orphan source national strategies*

[36] **INSAG Series No. 17** - *Independence in Regulatory Decision Making*

[37] **INSAG Series No. 20** - *Stakeholder Involvement in Nuclear Issues*

[38] **INSAG Series No. 21** - *Strengthening the Global Nuclear Safety Regime*

[39] **IAEA Legal Series No. 14** - *Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency Adopted on 26 September 1986 at the 18th 1986 plenary meeting*

VII. CSN Organizational Chart